UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated,

Plaintiff

v.

TAKEDA PHARMACEUTICAL CO. LTD., TAKEDA AMERICA HOLDINGS, INC., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., MYLAN, INC., MYLAN PHARMACEUTICALS, INC., ACTAVIS PLC, WATSON LABORATORIES, INC., RANBAXY LABORATORIES LTD., RANBAXY, INC., RANBAXY PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS USA, INC.

Defendants.

Civil Action No.

15 CV 3278

CLASS ACTION COMPLAINT AND JURY DEMAND

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I. INTRODUCTION

1. The direct purchaser plaintiff, American Sales Company, LLC ("ASC"), on behalf of itself and all others similarly situated (the "direct purchasers"), files this Class Action Complaint and Jury Demand against defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, "Takeda"), Mylan Inc. and Mylan Pharmaceuticals, Inc., (together, "Mylan"), Actavis plc f/k/a Actavis, Inc. and Watson Laboratories, Inc. (together, "Actavis"), Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., and Ranbaxy Pharmaceuticals, Inc., (collectively, "Ranbaxy"), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (together, "Teva"). Defendants Mylan, Actavis, Ranbaxy, and Teva will collectively be referred to as the "generic defendants." Takeda and the generic defendants will collectively be referred to as the "defendants." Based upon personal knowledge as to facts pertaining to them, and upon information and belief as to all other matters, the direct purchasers, though counsel, allege as follows:

II. NATURE OF THE ACTION

2. This action arises out of an overarching anticompetitive scheme by brand name drug maker Takeda and several of its ostensible generic competitors to allocate, and unreasonably delay competition in, two related drug markets—the market for pioglitazone hydrochloride tablets (sold by Takeda under the brand name ACTOS) and the market for the fixed dose combination product containing both pioglitazone hydrochloride and metformin (sold by Takeda under the brand name ACTO*plus* met). ACTOS is indicated for the improvement of glycemic control in patients with Type 2 diabetes, either as either a monotherapy treatment or a

combination therapy consisting of two separate drugs—pioglitazone hydrochloride together with sulfonylurea, metformin, or insulin. ACTO*plus* met is indicated as a fixed dose combination of pioglitazone hydrochloride and metformin to improve blood sugar control in adults with Type 2 diabetes who are already taking ACTOS and metformin separately, or taking metformin alone and it is not controlling blood glucose at normal levels.

3. ACTOS became one of Takeda's biggest selling products. By 2011, ACTOS and ACTO*plus* met together generated over $3 billion in annual sales.

4. Takeda knew, however, that the products were vulnerable to a rapid and near-complete loss of sales once less expensive generic versions entered the market.

5. In order to delay the onset of generic competition and squeeze more multi-billion-dollar years out of these products, Takeda devised a multi-part scheme which it enticed its would-be generic competitors to join.

6. **First**, Takeda submitted false and misleading patent information regarding two patents to the Food and Drug Administration (the "FDA") for publication in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to ACTOS. Takeda asserted in its patent information that the two patents—United States Patent Nos. 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent")—claim the ACTOS drug product. These patents plainly and unambiguously do not claim the ACTOS drug product, however. The '584 Patent claims a drug product consisting of pioglitazone hydrochloride *and* a biguanide. And, the '404 Patent claims a drug product consisting of pioglitazone hydrochloride *and* an insulin secretion enhancer.

7. The ACTOS drug product contains neither biguanide nor an insulin secretion enhancer, and thus neither the '584 Patent nor the '404 Patent claims the ACTOS drug product.

Indeed, Takeda has listed the '584 Patent in the Orange Book as claiming the drug product ACTO*plus* met, which does contain both pioglitazone hydrochloride and a biguanide, and has listed the '404 Patent in the Orange Book as claiming the drug product Duetact, which does contain both pioglitazone hydrochloride and an insulin secretion enhancer.

8. Among other intended anticompetitive effects, Takeda's submission of false and misleading patent information regarding the '584 Patent and '404 Patent for ACTOS permitted the first generic manufacturer that filed an Abbreviated New Drug Application ("ANDA") with a Paragraph IV certification[1] to claim the 180-day exclusivity provided by the Hatch-Waxman Act. That exclusivity prevented the FDA from approving any other generic ACTOS products for entry into the market until 180 days after the first-filers entered. Takeda's submission of false and misleading patent information thus created a "bottleneck" on FDA approval of *any* generic ACTOS products until the first generic filer entered the market. Later-filing generic manufacturers were automatically delayed due to the first-filer's 180-day exclusivity.

9. **Second**, Takeda exacerbated the economic harm caused by its false and misleading patent submission by paying the generic first-filers to delay entry. Having created the bottleneck, Takeda paid the first-filers to keep the bottleneck in place.

10. Generic competition for ACTOS was likely to begin immediately after ACTOS's drug substance patent—U.S. Patent No. 4,687,777 (the "'777 Patent")—expired on January 17, 2011. Without regard to whether the lawsuits had legal merit, Takeda sued every manufacturer that sought FDA approval to sell generic ACTOS.

[1] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

11. Defendants Mylan, Ranbaxy, and Actavis had all submitted Paragraph IV certifications with respect to the '584 Patent and the '404 Patent. And each was entitled to "shared" 180-day exclusivity for ACTOS. These defendants obtained a June 2010 trial date for their allegations that Takeda's patents allegedly covering ACTOS were invalid, unenforceable, or would not be infringed by their generic products. That trial date would have permitted Mylan, Ranbaxy, and/or Actavis to successfully conclude the patent litigation and enter the market on or about January 17, 2011.

12. Takeda knew there was a substantial risk that its infringement claims would not prevail in the litigation. Therefore, as the trial date approached, Takeda made large, unjustified payments to Mylan, Ranbaxy, and Actavis to withdraw their challenges to the patents and delay entry into the market. In exchange for these Exclusion Payments—*i.e.*, a share of the supracompetitive profits made possible by the absence of generic competition—Mylan, Ranbaxy, and Actavis agreed to delay entering the market until August 17, 2012. As planned, this delayed entry by the first-filers had the intended effect of extending the bottleneck on FDA approval of many additional generic manufacturers, all of which were prevented from entering the market until 180 days after August 17, 2012.

13. **Third**, Takeda repeated this same Exclusion-Payment ploy with respect to ACTO*plus* met. Takeda had listed the '584 Patent as a drug product patent claiming ACTO*plus* met, and had listed various other patents as applicable method-of-use patents. Without regard to whether the lawsuits had legal merit, Takeda sued every manufacturer that sought FDA approval to sell generic ACTO*plus* met. Defendant Mylan submitted the first ANDA with a Paragraph IV certification with respect to ACTO*plus* met and was thus eligible for the Hatch-Waxman Act 180-day exclusivity.

14. Takeda knew there was a substantial risk that its infringement claims under these patents would not prevail in the litigation. Therefore, as the Hatch-Waxman Act's 30-month stay on Mylan's approval[2] was set to expire, Takeda made large, unjustified payments to Mylan to withdraw its challenge to the patents and delay entry into the market. In exchange for these Exclusion Payments—*i.e.*, a share of the supracompetitive profits made possible by the absence of generic competition—Mylan agreed to delay entering the market until 2012. As planned, this delayed entry by the first-filer had the intended effect of extending the bottleneck on FDA approval of many additional generic manufacturers, all of which were prevented from entering the market until 180 days after Mylan entered.

15. **Fourth**, Takeda and Mylan, Ranbaxy, and Actavis took additional anticompetitive measures to ensure that defendant Teva did not unravel the anticompetitive schemes they had concocted. Teva had refused to submit a Paragraph IV certification with respect to the '584 Patent and '404 Patent regarding ACTOS on the ground that Takeda had improperly identified them as drug product patents covering ACTOS. Instead, Teva filed what is known as a "Section viii statement"[3] attesting that Teva did not seek FDA approval for a use covered by the patents that Takeda had listed in the Orange Book.

16. Without regard to whether the lawsuit had legal merit, Takeda sued Teva for infringement of the patents allegedly covering ACTOS and ACTO*plus* met. Had Teva prevailed in that lawsuit, it could have entered the market with generic ACTOS upon the expiration of the '777 Patent on January 17, 2011. Under the Hatch-Waxman Act, and pursuant to the relief that

[2] 21 U.S.C. § 355(j)(5)(B)(iii).

[3] *See* 21 U.S.C. § 355(b)(2)(B) & 21 U.S.C. § 355(j)(2)(A)(viii).

Teva sought in its counterclaims against Takeda, Teva would not have been subject to the 180-day exclusivity bottleneck that Takeda, Mylan, Ranbaxy, and Actavis had constructed and extended.

17. Teva, like Mylan, Ranbaxy, and Actavis, had secured a June 2010 trial date, which gave it time to obtain a favorable ruling before January 17, 2011. Rather than risk the unraveling of its anticompetitive scheme and agreements with Mylan, Ranbaxy, and Actavis, Takeda made large, unjustified payments to Teva to withdraw its challenge to the patents, stop contesting Takeda's submission of false patent information regarding the '584 Patent and '404 Patent for ACTOS, and delay entry into the market. In exchange for these Exclusion Payments—i.e., a share of the supracompetitive profits made possible by the absence of generic competition—Teva agreed to delay entering the market with generic ACTOS until August 17, 2012, and to delay entering the market with generic ACTO*plus* met until Mylan entered in 2012.

18. Defendants' unlawful schemes and Exclusion Payment Agreements were designed to and did in fact: (a) delay the entry of less expensive generic versions of ACTOS in the United States; (b) fix, raise, maintain, or stabilize the price of ACTOS and its generic equivalents; (c) permit Takeda to maintain a monopoly in the United States for ACTOS and its generic equivalents; (d) allocate 100% of the United States market for ACTOS and its generic equivalents to Takeda; (e) delay the entry of less expensive generic versions of ACTO*plus* met in the United States; and (f) fix, raise, maintain, or stabilize the price of ACTO*plus* met and its generic equivalents.

19. Plaintiff brings this action as a class action on behalf of all direct purchasers who directly purchased branded and/or generic ACTOS and/or ACTO*plus* met products since January

17, 2011 with respect to ACTOS and since February 25, 2011 with respect to ACTO*plus* met (*see* class definitions below).

20. Plaintiff asserts claims for compensatory and/or treble damages for violations of the laws enumerated below.

III. JURISDICTION AND VENUE

21. This action arises under sections 1 & 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a). Plaintiff seeks damages for its injuries, and those suffered by members of the direct purchaser class, resulting from the defendants' fraudulent and anticompetitive conduct and scheme that delayed the entry of generic drugs into the United States market.

22. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for each of the proposed classes exceeds $5,000,000, and at least one member of each of the putative classes is a citizen of a state different from that of one of the defendants. This Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331(federal question) and 1337(a) (antitrust), and 15 U.S.C. § 15 (antitrust).

23. Defendants are subject to personal jurisdiction in this Court, including general and specific jurisdiction.

24. This Court has general jurisdiction over each defendant because one or more of the defendants has engaged in such a continuous and systematic course of business in this District as to render it at home in New York, sufficient to satisfy both C.P.L.R. §301 and the requirements of due process. Such course of business includes, but is not limited to:

a. One or more of the defendants has employees, offices and/or facilities in New York;

b. One or more of the defendants actively solicits business in and derives substantial sales and revenue from New York;

c. One or more of the defendants has substantial and ongoing business relationships with New York customers, employees and/or companies; and

d. One or more of the defendants is registered with the New York State Department of State to do business in New York, as a so-called foreign corporation.

25. This Court has specific jurisdiction over each defendant because one or more of the defendants purposefully directed its unlawful anticompetitive activities in New York and this lawsuit results from injuries that arise out of and relate to those New York activities, sufficient to satisfy both C.P.L.R. §302 and the requirements of due process. Such New York activities include, but are not limited to, those relating to the Exclusion Payment Agreements that are the subject matter of this action and which: (i) were negotiated, in part, here in New York, (ii) arose out of and resulted in the termination of underlying patent litigation that was pending here in this District; (iii) established that New York law governs their construction; and (iv) provide that the defendants consented to the jurisdiction of this Court in connection with any action arising out of or in connection with these Agreements.

26. One or more of the defendants sold the pharmaceutical products at issue in New York at supra-competitive prices, received substantial revenue from the sale of these products in New York and therefore reaped the benefits of its conduct from New York.

27. One or more of the defendants agreed to the jurisdiction of this Court in the underlying patent litigations.

28. Venue is appropriate in this district under 28 U.S.C. §1391(b) and (c) because defendants transact business within this district, and the interstate trade and commerce described

herein is carried out, in substantial part, in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) and (c) (general venue provisions).

IV. PARTIES

A. Plaintiff

29. Plaintiff American Sales Company, LLC ("ASC" or "plaintiff") is a Delaware limited liability company with its principal place of business in Lancaster, NY. ASC brings this action on its own behalf and as an assignee of McKesson Corporation which, during the relevant period, purchased ACTOS and ACTO*plus* met directly from its manufacturer, and as a representative of all entities similarly situated. ASC suffered and continues to suffer antitrust injury as a result of defendants' unlawful conduct.

B. Defendants

30. Defendant Takeda Pharmaceutical Company Limited is a Japanese company with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645.

31. Defendant Takeda America Holdings, Inc. is a wholly-owned subsidiary of defendant Takeda Pharmaceutical Company Limited, and is the United States parent corporation of defendants Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. Defendant Takeda America Holdings, Inc. is a corporation organized under the law of the State of New York with its principal place of business at 767 Third Avenue, New York, New York 10017.

32. Defendant Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

33. Defendant Takeda Development Center Americas, Inc., formerly known as Takeda Global Research and Development Center, Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

34. The foregoing defendants will collectively be referred to as "Takeda."

35. Defendant Mylan, Inc., formerly known as Mylan Laboratories, Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

36. Defendant Mylan Pharmaceuticals, Inc. is a corporation organized under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

37. The foregoing "Mylan" defendants will together be referred to as "Mylan."

38. Defendant Actavis plc is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland, and its United States place of business in Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. as a result of Watson Pharmaceuticals, Inc.'s acquisition of Swiss-based Actavis Group in or around October 2012. On or about October 1, 2013, Actavis, Inc. changed its name to Actavis plc.

39. Defendant Watson Laboratories, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Defendant Watson Laboratories, Inc. was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc.

40. The foregoing defendants will together be referred to as "Actavis."

41. Defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") was a corporation that, until March 25, 2015, was organized and existed under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Ranbaxy Labs was the parent company to the entire Ranbaxy business empire, which was, until March 2015, the largest generic drug manufacturer in India. It controlled manufacturing, research, and development, as well as the conduct and functioning of its Indian-based facilities, including a facility located at Paonta Sahib, India.

42. Defendant Ranbaxy, Inc. is a corporation that is organized and exists under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Inc. was responsible for (a) communications with the FDA on behalf of Ranbaxy Labs and its related entities; (b) prosecution of ANDAs on behalf of Ranbaxy Labs; and (c) management of US litigation on behalf of Ranbaxy Labs and its related entities. At all relevant times, Ranbaxy, Inc. acted in its own right and as an agent of defendant Ranbaxy Labs.

43. Defendant Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of defendant Ranbaxy, Inc. Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

44. Defendant Sun Pharmaceutical Industries Limited ("Sun Pharma") is a public limited company incorporated under the laws of India with its registered office at Sun Pharma Advanced Research Centre (SPARC), Tandalja, Vadodara – 390 020, Gujarat, India and its corporate office is at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai – 400 059, Maharashtra, India. Sun Pharma is an international, integrated, specialty pharmaceutical

company. Pursuant to a Scheme of Arrangement between Ranbaxy Labs and Sun Pharm approved by the two companies' boards on April 6, 2014, and completed on or about March 25, 2015, Ranbaxy Labs was merged into Sun Pharma, and all liabilities of Ranbaxy Labs, including contingent liabilities, have been transferred to and vested in Sun Pharm.

45. On April 6, 2014, Sun Pharma and Ranbaxy Labs announced that they had entered into an agreement pursuant to which Sun Pharma would acquire Ranbaxy in an all-stock merger transaction. This transaction was approved by the boards of directors of both companies on the same day.

46. The Scheme of Arrangement approved by the companies and pursuant to which the merger took place provides that:

> All the liabilities including all secured and unsecured debts, whether in Indian rupees or foreign currency), sundry creditors, contingent liabilities, duties, obligations and undertakings of [Ranbaxy Laboratories Limited] of every kind, nature and description whatsoever and howsoever arising, raised or incurred or utilized for its business activities and operations (the "Liabilities") shall, without any further act, instrument or deed, be and the same shall stand transferred to and vested in or deemed to have been transferred to and vested in the Transferee Company without any further act, instrument or deed, along with any charge, lien, encumbrance or security thereon….

47. On May 6, 2014, Sun Pharma and Ranbaxy Labs provided notice of the proposed merger to the Competition Commission of India. After investigating the proposed merger, the Commission approved the proposed merger on December 5, 2014, subject to the companies' divesture of certain products. Sun Pharma and Ranbaxy Labs also agreed to divest Ranbaxy Labs' generic minocycline tablets to Torrent Pharmaceuticals, in response to a complaint brought by the United States Federal Trade Commission.

48. Sun Pharma completed its acquisition of Ranbaxy on or about March 25, 2015 and now owns Ranbaxy. Ranbaxy Labs is no longer listed on the Indian Stock Exchanges.

49. Herein, "Ranbaxy" refers to defendants Ranbaxy Labs, Ranbaxy Inc., and Ranbaxy Pharmaceuticals, and Sun Pharma, collectively.

50. Defendant Teva Pharmaceutical Industries, Ltd., one of the largest pharmaceutical companies in the world, is headquartered in Petah Tikva, Israel.

51. Defendant Teva Pharmaceuticals USA, Inc. is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

52. The foregoing defendants will together be referred to as "Teva."

53. All of defendants' wrongful actions described in this complaint are part of, and in furtherance of, the anticompetitive scheme and anticompetitive agreements (as further described below), and were authorized, ordered, and/or executed by defendants' various officers, agents, employees, and/or other representatives while actively engaged in the management of defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with defendants' actual, apparent, and/or ostensible authority.

V. INDUSTRY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs, Listing Patent Information in the Orange Book, and the Substitution of Generic Drugs for Brand Name Drugs

54. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), branded drug manufacturers must obtain FDA approval to sell a new drug product by filing a New Drug

Application ("NDA").[4] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on any applicable patents.[5]

55. When the FDA approves a branded drug manufacturer's NDA, the manufacturer may list in the Orange Book any patents the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug before the expiration of the listed patents. The branded drug manufacturer may also list in the Orange Book any patents issued after the FDA approved the NDA within thirty days of their issuance.[6]

56. The FDA relies completely on a branded drug manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify a branded drug manufacturer's patents and patent information for accuracy or trustworthiness. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

57. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs.[7] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in a branded drug manufacturer's original NDA, but must further show that the generic drug

[4] 21 U.S.C. §§ 301–392.

[5] 21 U.S.C. § 355(a), (b).

[6] 21 U.S.C. § 355(b)(1) & (c)(2).

[7] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

(i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and (ii) is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

58. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its branded counterpart.[8]

59. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

60. The Hatch-Waxman Act achieved both goals by advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for branded drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984,

[8] 21 U.S.C. § 355(j)(8)(B).

annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total annual prescription drug revenue had soared to $300 billion.

2. Requirements for Submitting Patent Information

61. The regulatory structure created by the Hatch-Waxman Act includes a process for identifying and addressing patents that arguably apply to brand and generic drug products. This regulatory structure requires the holder of an NDA to submit information concerning its patents to the FDA, which incorporates the information into the Orange Book. Patent information is listed in the Orange Book for each NDA to which the patent may apply. Then, when a generic company seeks to file an ANDA, it must submit patent certifications or statements, described more fully below, to each patent listed in the Orange Book for the NDA that is the reference listed drug for the ANDA.

62. Under the Hatch-Waxman Act, the NDA holder must submit certain required information concerning "any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[9]

63. When Takeda submitted patent information regarding the '584 Patent and '404 Patent for ACTOS—in 1999 and 2002, respectively—the relevant statute required the NDA applicant to list "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of

[9] 21 U.S.C. § 355(b)(1)(G).

patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[10]

64. The then-applicable regulations identified three types of patents that could properly be listed: "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents."[11] The regulations further provided that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product."[12] The NDA holder also could properly list a patent for a drug product only "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale *of the drug product*."[13] In short, for patents that claimed a drug product, the NDA applicant could submit information describing the patent as a "drug product patent" only if the patent claimed the drug product that was the subject of the NDA. The patent's drug product claim could claim not just *some* drug product—it had to claim the *relevant* drug product, *i.e.*, the FDA approved drug product as to which the NDA applicant listed the patent.

65. NDA applicants were on their honor to properly identify the "Type of patent, *i.e.*, drug, drug product, or method of use."[14] The FDA expressly refused to police the proper listing

[10] 21 U.S.C.A. § 355(b)(1) (1999) & (2002).

[11] 21 C.F.R. § 314.53(b) (1999) & (2002).

[12] *Id.* (emphasis added).

[13] *Id.* (emphasis added).

[14] 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).

of patents and patent information, noting that it "does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA," and that it "believes that the declaration requirements under § 314.53(c) [requiring the applicant to declare "that Patent No. ____ covers the formulation, composition, and/or method of use of (name of drug product)"], as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted."[15]

66. Important regulatory and competitive consequences flow from the distinction between patents described as containing relevant drug product claims, and patents described as containing only method-of-use claims. If the patentee describes the patent in the patent information as containing a relevant drug product claim, an ANDA applicant desiring to market its generic product before the patent expires must file a Paragraph IV certification, certifying that the patent is invalid, unenforceable, or would not be infringed by the generic product.[16] The patentee and/or NDA holder then has the opportunity to obtain an automatic 30-month stay on generic competition by filing a patent infringement lawsuit against the ANDA applicant. In addition, and of particular importance here, the FDA is prohibited from approving a subsequent applicant's ANDA until 180 days after the first-filer has entered the market.[17] This 180-day exclusivity creates a "bottleneck" that delays *all* generic competition until 180 days after the first-filer enters the market.

[15] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994).

[16] 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

[17] 21 U.S.C. § 355(j)(5)(B)(iv).

67. By contrast, if the patentee describes the patent as containing only relevant method-of-use claims, in certain circumstances an ANDA applicant can submit what is known as a "Section viii statement."[18] In a Section viii statement, the ANDA applicant states that it is not seeking approval for the particular use covered by the method-of-use patent. If an ANDA applicant makes only a Section viii statement, then the patentee or NDA holder *cannot* obtain an automatic 30-month stay on generic competition even if it sues the ANDA applicant for patent infringement. And the FDA can approve an ANDA containing only a Section viii statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

68. Whether a patent actually claims the relevant drug product is irrelevant for purposes of Paragraph IV certifications. Rather, FDA regulations and instructions made unmistakably clear that the *patent information* submitted by the NDA applicant determined whether generic manufacturers would be permitted to make Paragraph IV certifications and thus would be eligible for the 180-day exclusivity period.[19]

69. In short, describing a patent as containing a relevant drug product claim gives the patentee two key competitive advantages—an automatic 30-month stay on generic competition, and a bottleneck that delays all generic competition until 180 days after the first generic filer enters the market.

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[18] 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii).

[19] *See, e.g.*, FDA Proposed Rule, *Abbreviated New Drug Application Regulations*, 54 FR 28872, at 28885 (July 10, 1989) ("the patent information submitted to FDA, whether or not published in the list, should be the basis of the [generic company's] certification"); 21 C.F.R. § 314.94(a)(12)(iii) (ability to submit only a Section viii statement is based on "patent information … submitted under … § 319.53").

3. Paragraph IV Certifications

70. Where the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify that the generic drug will not infringe those patents. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the branded drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the branded drug has expired (a "Paragraph II certification");

iii. that the patent for the branded drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the branded drug is invalid or will not be infringed by the generic drug manufacturer's proposed product (a "Paragraph IV certification").

71. If a generic drug manufacturer files a Paragraph IV certification, a branded drug manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic drug manufacturer filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic drug manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

72. As an incentive to generic drug manufacturers to seek approval of generic alternatives to branded drugs, the first generic drug manufacturer to file an ANDA containing a Paragraph IV certification typically receives a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made before December 8, 2003, the first generic drug manufacturer applicants received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. For Paragraph IV certifications made after December 8, 2003, the first generic drug manufacturer applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means the first approved generic drug is the only available ANDA-based generic drug for at least six months.

73. Branded drug manufacturers can "game the system" by describing patents as containing relevant drug product claims (even if the patents, in fact, do not do so) and suing any generic drug manufacturer competitor filing an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug—is demonstrated by the fact that generic drug manufacturers have prevailed in Paragraph IV Litigation in cases involving 73% of the drug products studied, either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal of the suit.

74. For Paragraph IV certifications made before December 8, 2003, the first ANDA applicant could help a branded drug manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic drug manufacturers. In exchange

for payments from the branded drug manufacturer, the first generic drug manufacturer applicant could agree to delay marketing its generic drug, thereby extending the 180-day exclusivity bottleneck.

75. On December 8, 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") to make it more difficult for branded drug and generic drug manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic drug products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

76. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

77. Branded drug manufacturers and first-filing generic drug manufacturers can structure their settlements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place. For example, they can settle their litigation before a

final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seek a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic drug manufacturer filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the branded drug manufacturer did not assert against it in a Paragraph IV Litigation.

B. The Benefits of Generic Drugs

78. Generic versions of branded drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their branded counterparts. The only material difference between generic drugs and branded drugs is their price: generic drugs are usually at least 25% less expensive than their branded drug counterparts when there is a single generic drug competitor. The discount typically increases to 50% to 80% (or more) when there are multiple generic drug manufacturer competitors in the market for a given branded drug. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, competition from generic drugs is viewed by branded drug manufacturers, such as Takeda, as a grave threat to their bottom lines.

79. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially

substitute the generic drug when presented with a prescription for the branded drug. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

80. There is an incentive to choose the less expensive generic drug equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic drugs than on branded drugs. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic drugs for more expensive branded drugs. Health insurers are contractually obligated to pay for the bulk of their insureds' prescriptions, whether filled with branded drugs or generic drugs, so they offer lower copays for generic drugs in order to encourage their use.

81. Generic drug competition enables all putative class members to (i) purchase generic versions of a drug at substantially lower prices; and/or (ii) purchase a branded drug at a reduced price.

82. Until the generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for, and compete with, the branded drug, and, therefore, the branded drug manufacturer can continue to profitably charge supracompetitive prices. Brand drug manufacturers, such as Takeda, which are well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the introduction of generic drug competition into the market, including through tactics such as the improper patent listing and Exclusion Payment Agreements.

C. The Impact of Authorized Generics

83. The 180-day marketing exclusivity to which first-filer generic drug manufacturers may be entitled does not prevent a branded drug manufacturer from marketing its own generic drug alternative to the branded drug during the 180-day period. Such an "authorized generic" is chemically identical to the branded drug, but is sold as a generic drug through either the branded manufacturer's subsidiary (if it has one) or through a third-party generic drug manufacturer. Competition from an authorized generic drug during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

84. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the FTC found that authorized generic drugs capture a significant portion of sales, reducing the first-filer generic drug manufacturer's revenues by approximately half on average during the 180-day exclusivity period. The first-filing generic drug manufacturer makes significantly less money when it faces competition from an authorized generic because (i) the authorized generic drug takes a large share of unit sales away from the first filer; and (ii) the presence of an additional generic drug in the market causes prices to decrease.

85. Although first-filing generic drug manufacturers make significantly less money when they must compete with an authorized generic drug during the first 180 days, consumers and other drug purchasers, such as plaintiff and members of the putative direct purchaser class, benefit from the lower prices caused by competition between the authorized generic drug manufacturer and the first-filing generic drug manufacturer.

86. Given the significant negative impact of an authorized generic drug manufacturer on the first-filing generic drug manufacturer's revenues, a branded drug manufacturer's

agreement not to launch an authorized generic drug has tremendous monetary value to the generic drug manufacturer. Branded drug manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers, such as plaintiff and members of the putative direct purchaser class, of the lower prices resulting from two forms of competition: (i) between the branded drug and the generic drug; and (ii) between the generic drugs.

VI. FACTS

A. The '777 Patent issues, and ACTOS is launched.

87. On August 18, 1987, the United States Patent and Trade Office (the "PTO") issued to inventors Kanji Meguro and Takeshi Fujita U.S. Patent No. 4,687,777 (the "'777 Patent") entitled "Thiazolidinedione Derivatives, Useful As Antidiabetic Agents." The patent was at first assigned to Takeda Chemical Industries, Ltd., and then later to another Takeda entity. The '777 Patent purports to claim the novel compound commonly known under the nonproprietary name "pioglitazone" and its pharmacologically acceptable salts including pioglitazone hydrochloride, the active ingredient for ACTOS. Because both ACTOS and ACTO*plus* met use as an active pharmaceutical ingredient pioglitazone, each of those products are covered by the '777 Patent. After accounting for applicable extensions, the '777 was set to expire on January 17, 2011.

88. On January 15, 1999, Takeda submitted to the FDA NDA 021073, seeking approval to manufacture, market, and sell ACTOS, which contains the active ingredient pioglitazone hydrochloride, and is used to improve glycemic control in adults with Type 2 diabetes when diet and exercise are not sufficient.

89. On July 15, 1999, the FDA approved Takeda's NDA for the use of ACTOS to improve glycemic control in adults with Type 2 diabetes – either as monotherapy or in combination with a sulfonylurea, metformin, or insulin.

90. As permitted by the FDCA and applicable regulations, Takeda submitted the '777 Patent for listing in the Orange Book as a drug substance patent covering ACTOS.

91. Following the July 15, 1999 FDA approval, Takeda launched ACTOS into the U.S. market.

92. At the time of the launch, the FDA had determined, at Takeda's request, that the NDA for ACTOS tablets (NDA 021073) had a new chemical entity ("NCE"). As such, Takeda was entitled to NCE exclusivity that prevents the submission of an ANDA until expiration of five years from NDA approval (which, for ACTOS, meant the exclusivity expired on July 15, 2004). However, if an ANDA applicant certifies that one or more of the patents listed for the reference listed drug ("RLD") is invalid or not infringed (*i.e.*, files a Paragraph IV certification to the patent), then the ANDA may be submitted one year earlier. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

93. In short, when ACTOS was approved in July of 1999, Takeda knew (i) that it had NCE exclusivity such that the first ANDAs (if based on Paragraph IV certifications) would be filed as early as July 15, 2003, (ii) that it had ostensible compound patent coverage for the active pharmaceutical ingredient pioglitazone until January 17, 2011, but (iii) that when efforts to gain generic entry began as early as July 15, 2003, it would have no legitimate, practical basis to exclude competition beyond January 17, 2011. It also knew that successful entry of generics, whether before or after the '777 basic compound patent expired, would likely mean the near complete loss of sales from the ACTOS product.

B. The ’584 Patent and the ’404 Patent are issued, and Takeda wrongfully lists them in the Orange Book.

94. During the 1990s, Takeda employees explored ways to develop products that were to be used in combination with pioglitazone.

95. On October 12, 1999, the PTO issued United States Patent Nos. 5,965,584 (the “’584 Patent”) entitled “Pharmaceutical Composition.” The patent was assigned to Takeda Chemical Industries, Ltd. and later to a different Takeda entity. The ’594 patent purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* a biguanide (*e.g*., metformin) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof *in combination with a biguanide* (*e.g*., metformin). The ’584 Patent expires on June 19, 2016.

96. The ’584 Patent does not claim the compound pioglitazone (the active ACTOS drug ingredient); at most, the ’584 Patent claims a method of using pioglitazone in combination with another active ingredient, metformin. As a result, the ’584 Patent does not conceivably cover a standalone pioglitazone drug product, and thus would not cover ACTOS. Takeda knew this. The ’584 patent only potentially covers a combination product using both those ingredients. As such, the ’584 arguably covers what eventually would be sold by Takeda as ACTO*plus* met as the purported commercial embodiment of the ’584 Patent.

97. On or about November 5, 1999 – and despite knowing its newly acquired ’584 Patent in no legitimate way could be read to cover ACTOS, but aware that sales from its promising new ACTOS franchise would likely be wiped out by generic entry upon the expiration of the ’777 Patent – Takeda filed information with the FDA stating that the ’584 Patent claimed both the “drug product” ACTOS and its “method of use,,” and Takeda thereby caused the ’584

Patent to be listed in the Orange Book as covering ACTOS. In doing so, Takeda knowingly and falsely submitted patent information to the FDA describing the '584 Patent as a drug product patent *that claims ACTOS*. When submitting the '584 Patent information to the FDA, Takeda knew that the information was false and misleading. Takeda acted with the purpose and effect of impairing competition from generic, and it did so for the specific purpose of seeking to extend its monopoly beyond January 17, 2011.

98. On December 11, 2001, the PTO issued U.S. patent No. 6,329,404 (the "'404 Patent") entitled "Pharmaceutical Composition." The patent was assigned to Takeda Chemical Industries, Ltd. and later to a different Takeda entity. The '404 Patent purports to claim a pharmaceutical composition comprising pioglitazone or salts thereof *in combination with* an insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with an insulin secretion enhancer. The '404 Patent expires on June 19, 2016.

99. The '404 Patent did not claim the compound pioglitazone (the active ACTOS drug ingredient); at most, the '404 Patent claims a method of using pioglitazone in combination with another active ingredient, insulin secretion enhancer (*e.g.*, a sulfonylurea, such as glimepiride). As a result, the '404 Patent does not conceivably cover a standalone pioglitazone drug product, and thus would not cover ACTOS. Takeda knew this. The '404 Patent only potentially covers a combination product using both those ingredients. As such, the '404 arguably covers what eventually would be sold by as Duetact (not ACTOS or ACTO*plus* met), is the purported commercial embodiment of the '404 Patent.

100. On or about January 3, 2002 – and despite knowing that its newly acquired '404 Patent could in no legitimate way be read to cover ACTOS, but aware that the huge sales Takeda was now achieving from its ACTOS franchise (now two years in an booming) would likely be wiped out by generic entry upon the expiration of the '777 Patent, Takeda submitted patent information with the FDA stating that the '404 Patent claimed both the "Drug Product" ACTOS and its "Method of Use", and Takeda thereby caused the '404 Patent to be listed in the Orange Book as covering ACTOS. In doing so, Takeda knowingly and falsely submitted patent information to the FDA describing the '404 Patent as a drug product patent *that claims ACTOS*. Takeda acted with the purpose and effect of impairing competition from generic, and it did so for the specific purpose of seeking to extend its monopoly beyond January 17, 2011.

101. In addition to the '777 Patent, the '584 Patent, and the '404 Patent, Takeda submitted eight other patents to the FDA for listing in the Orange Book::

Patent No.	**Issue Date**	**Patent Expiry**
6,150,383 (the "'383 Patent")	November 21, 2000	June 19, 2016
6,150,384 (the "'384 Patent")	November 21, 2000	June 19, 2016
6,166,042 (the "'042 Patent")	December 26, 2000	June 19, 2016
6,166,043 (the "'043 Patent")	December 26, 2000	June 19, 2016
6,172,090 (the "'090 Patent")	January 9, 2001	June 19, 2016
6,211,205 (the "'205 Patent")	April 3, 2001	June 19, 2016
6,271,243 (the "'243 Patent")	August 7, 2001	June 19, 2016
6,303,640 (the "'640 Patent")	October 16, 2001	August 9, 2016

These patents (the "ACTOS Method-of-Use Patents") claimed various methods of using ACTOS in combination with other drug products (such as biguanide or an insulin secretion enhancer) to treat various conditions or to reduce various side effects. Takeda listed the Method-of-Use Patents in the Orange Book as method of use patents, not drug substance or drug product patents.

102. Under both the Hatch-Waxman Act and the FDA's implementing regulations, the drug product claims of the '584 Patent and the '404 Patent do not form a permissible basis for

Takeda to submit patent information describing the patents as drug product patents covering ACTOS.

103. *First*, Takeda could properly identify the '584 Patent and the '404 Patent as drug product patents claiming ACTOS only if the patents in fact claimed the ACTOS drug product. The patents unequivocally do not do so. The *only* active ingredient in ACTOS is pioglitazone hydrochloride. By contrast, the drug product claims in the '584 Patent and the '404 Patent claim drug products containing *both* pioglitazone *and* certain additional active ingredients—biguanide or an insulin secretion enhancer, respectively. Neither patent claims a drug product that contains pioglitazone as its sole active ingredient. Thus, the patents do not claim the ACTOS drug product as a matter of law.

104. *Second*, Takeda could not reasonably assert the drug product claims of the '584 Patent or the '404 Patent against generic drug manufacturers seeking to market ACTOS. The patents claimed only drugs *other* than the ACTOS drug product. In fact, it would be impossible for any ANDA referencing the ACTOS NDA to get FDA approval of a drug containing either of the compositions claimed in the '584 Patent and '404 Patent. (In patent litigation to be described below, Takeda would eventually concede the inapplicability of the '584 Patent and the '404 Patent for ACTOS generics when it withdrew infringement claims based on those patents before a court could rule on them).

105. Takeda's wrongful listing of the '584 Patent and the '404 Patent in the Orange Book as covering ACTOS had several impacts on the regulatory paths available for generic entry. First, a would-be maker for generic ACTOS might see itself as needing to file a certification of some sort with respect to those patents (e.g., a Paragraph IV certification that the patents were invalid, unenforceable or not infringed, or some other form of certification).

Second, if a Paragraph IV certification were made, Takeda would be able to file an infringement lawsuit based on the technical act of infringement, and a would-be generic maker proceeding by way of a Paragraph IV certification would (if timely sued by Takeda for infringement) need to await approval until expiration of the sixty-month stay. Third, the fact that the patents had been listed in the Orange Book meant that the *first* generic applicant(s) to file an ANDA would gain the 180-day exclusivity for ANDA-approved generics. In effect, the wrongful listing of the '584 and '404 created an opportunity for one (or more) first filer generics to enjoy a 180-day exclusivity right (and ability to bottleneck competitors' applications) for ACTOS that otherwise would not have existed.

C. The first wave ACTOS generic applications are filed.

106. Generic drug manufacturers were eager to apply for FDA approval to market generic versions of ACTOS.

107. On July 15, 2003 – the first day generics could do so given the NCE status of ACTOS – four generic manufacturers, Mylan, Ranbaxy, Actavis and Alphapharm, each filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTOS.

108. Of course, Mylan, Ranbaxy and Actavis are separate generic companies, and they are supposed to be *competitors* with each other, and with Takeda. Their ANDAs were filed on the same day because that is the earliest date each of them, acting separate could do so, and because (at least at this time) they were acting as generic makers should – seeking to enter as early as they can, and ahead of the competition. (Mylan subsequently acquired Alphapharm before generic ACTOS was launched, and so this complaint does not separately describe facts as to the Alphapharm ANDA).

109. The Mylan ANDA, which was assigned ANDA No. 076801, contained a Paragraph IV certification as to the ’777 Patent, the ’584 Patent and the ’404 Patent, and Section viii statements as to the ACTOS Method-of-Use Patents.

110. By letter dated September 8, 2003, Mylan notified Takeda that Mylan had filed ANDA No. 076801 seeking to manufacture, market, and sell a generic version of ACTOS and that the ANDA contained a Paragraph IV certification as to the ’777 Patent, ’584 Patent and ’404 Patent, and Section viii statements as to the ACTOS Method-of-Use Patents.

111. As accepted for filing by the FDA, the Actavis ANDA, which was assigned ANDA No. 076798, contained a Paragraph III certification as to the ’777 Patent, a Paragraph IV certification as to the ’584 Patent and the ’404 Patent, and Section viii statements as to the ACTOS Method-of-Use Patents.

112. By letter dated September 9, 2003, Actavis notified Takeda that Actavis had filed ANDA No. 076798 seeking to manufacture, market, and sell a generic version of ACTOS and that the ANDA contained a Paragraph III certification as to the ’777 Patent, a Paragraph IV certification as to the ’584 Patent and ’404 Patent, and Section viii statements as to the ACTOS Method-of-Use Patents.

113. The Ranbaxy ANDA, which was assigned ANDA No. 076800, contained a Paragraph III certification as to the ’777 Patent, a Paragraph IV certification as to the ’584 Patent and the ’404 Patent, and Section viii statements as to the ACTOS Method-of-Use Patents.

114. By letter dated September 18, 2003, Ranbaxy notified Takeda that Ranbaxy had filed ANDA No. 076800 seeking to manufacture, market, and sell a generic version of ACTOS and that the ANDA contained a Paragraph III certification as to the ’777 Patent, a Paragraph IV

certification as to the ’584 Patent and ’404 Patent, and Section viii statements as to the ACTOS Method-of-Use Patents.

115. As a result of these filings, each of the first wave generics – Mylan, Ranbaxy and Actavis – chose to address the impediments presented by the Orange Book listings of the ’584 Patent and the ’404 Patent by submitting Paragraph IV certifications as to those patents. By doing so, each took advantage of the opportunity that should not have existed by reason of Takeda’s wrongful listing of those patents – the chance to be treated as “first-to-file” ANDA applicants entitled to enjoy 180-day exclusivity from other generic company ANDA-approved sales, and the ability to bottleneck the entry of other generics (subject to certain exceptions, which will be addressed later) until such time as one of these first wave filers chose to launch its generic. The FDA ultimately concluded that Mylan, Ranbaxy, and Actavis were entitled to “shared” 180-day exclusivity with respect to generic ACTOS; each had first-to-file exclusivity (subject to exceptions) from non-first wave generic makers for the first six months from when the first of any one of the first wave filers chose to launch their generic product (assuming the company had final approval from the FDA, of course).

116. On October 17, 2003, Takeda filed three separate suits in the United States District Court for the Southern District of New York: *Takeda Chemical Industries, Ltd, et al. v. Ranbaxy Laboratories, Ltd, et al.*, Civil Action No. 1:03-cv-08250-DLC (S.D.N.Y.); *Takeda Chemical Industries, Ltd., et al. v. Mylan Laboratories Inc., et al.*, Civil Action No. 1:03-cv-08253-DLC (S.D.N.Y.); and *Takeda Chemical Industries, Ltd, et al. v. Watson Pharmaceuticals, Inc., et al.*, Civil Action No. 1:03-cv-08254-DLC (S.D.N.Y.). Takeda alleged that Ranbaxy’s, Mylan’s and Actavis’ generic ACTOS products would infringe the drug product claims of the ’584 Patent and ’404 Patent, pursuant to 35 USC § 271(e)(2)(A), and induce infringement of the

method-of-use claims of the ’584 Patent and ’404 Patent and certain of the ACTOS Method-of-Use Patents, pursuant to 35 USC § 271(b). Takeda also alleged that Mylan’s generic ACTOS product would infringe the ’777 Patent, pursuant to 35 USC § 271(e)(2)(A). Takeda filed the patent infringement cases against Mylan, Actavis, and Ranbaxy without regard to the merits of the cases with respect to the ’584 Patent and ’404 Patent.

117. During the litigation, Mylan, Actavis, and Ranbaxy secured substantial evidence via discovery supporting a host of defenses focusing on: (i) the enforceability of the ’584 Patent and ’404 Patent; (ii) the validity of the ’584 Patent and the ’404 Patent; and (iii) the strength of Takeda’s infringement allegations regarding the ’584 Patent, the ’404 Patent and the ACTOS Method-of-Use Patents. Indeed, before the scheduled trial in June 2010 with respect to the ’584 Patent and the ’404 Patent, Takeda withdrew its allegations that Mylan, Actavis, and Ranbaxy’s generic ACTOS products infringed the drug product claims of the ’584 Patent and ’404 Patent.

118. To prevent generic entry using just the strength of its the ’584 Patent, the ’404 Patent and the ACTOS Method-of-Use Patents, Takeda would have had to defeat each of Mylan’s, Ranbaxy’s, and Actavis’ arguments regarding direct and indirect infringement of those patents. Takeda instead would later decide to protect its monopoly by paying Mylan, Ranbaxy, and Actavis to withdraw their defenses to those patents and delay introducing their generic ACTOS products.

D. The Teva generic ACTOS application is filed.

119. In the 2000s, Israel-based Teva had grown to become one of the world’s largest drug makers, focusing on finished generic products.

120. On or around July 14, 2004, Teva filed ANDA No. 077210, seeking to manufacture, market and sell generic versions of ACTOS.

121. The Teva ANDA contained a Paragraph III certification as to the '777 Patent, which meant Teva would not seek to market its generic product before the January 17, 2011 expiration of the patent. Teva refused, however, to submit a Paragraph IV certification with respect to the '584 Patent and the '404 Patent. Instead, with respect to those patents, as well as the Method-of-Use Patents, Teva included only Section viii statements. As permitted by applicable regulations, the Section viii statements asserted that Teva's label for its generic ACTOS would "carve out" information regarding methods of using ACTOS in combination with a biguanide or an insulin secretion enhancer (the methods of use claimed by the '584 Patent and '404 Patent, respectively) or other uses covered by the Method-of-Use Patents.

122. Teva's decision not to include a Paragraph IV certification with respect to the '584 Patent and the '404 Patent raised the possibility that the FDA could approve Teva's ANDA without regard to whether any other ANDA applicant was otherwise entitled to a 180-day exclusivity period with respect to ACTOS. In other words, Teva's Section viii strategy set up the real potential for Teva to leap frog over the first wave ACTOS generic filers – Mylan, Ranbaxy, and Actavis – and launch a generic version of ACTOS once the '777 Patent expired in January 2011.

123. Because the Teva ANDA did not contain a Paragraph IV certification with respect to any Orange Book-listed patent for ACTOS, Teva was not required to, and so did not, send a notice letter to Takeda regarding the Teva ANDA.

E. The challenge to the '777 Patent is tried.

124. Following discovery, the Takeda actions against Mylan, Ranbaxy and Actavis were consolidated. The Court hearing the consolidated action opted to try Mylan's challenge to the '777 Patent before considering the other asserted patents.

125. After a bench trial held in January 2006, the Court found that the '777 Patent was not invalid due to obviousness and that Takeda had not engaged in inequitable conduct in obtaining the patent.[20] This decision was upheld by the United States Court of Appeals for the Federal Circuit in June 2007.[21]

126. The decision on the '777 patent had no bearing to the merits of Takeda's infringement claims based on the '584 and '404 patents, nor did it have any bearing on whether Takeda had wrongfully listed those patents in the Orange Book.

F. Takeda gains approval for ACTO*plus* met and launches the product.

127. By the fall of 2004, Takeda's efforts to find a line extension product for ACTOS had developed a combination product using both pioglitazone and metformin.

128. On October 27, 2004, Takeda submitted NDA 021842, seeking FDA approval to manufacture, market, and sell a fixed single dose combination of pioglitazone hydrochloride and metformin hydrochloride designed to improve glycemic control in adults with Type 2 diabetes, which Takeda subsequently marketed as ACTO*plus* met.

129. On August 29, 2005, the FDA approved Takeda's NDA for ACTO*plus* met. Takeda listed the '584 Patent in the Orange Book as a drug product patent for ACTO*plus* met, and listed three additional patents – the '042 Patent, the '043 Patent, and the '090 Patent – as applicable method-of-use patents (the "ACTO*plus* met Method-of-Use Patents"). Each of the ACTO*plus* met Method-of-Use Patents are also listed as one of the ACTOS Method-of-Use Patents.

[20] *Takeda Chem. Indus., Inc. v. Mylan Labs., Inc.*, 417 F. Supp. 2d 341 (S.D.N.Y. 2006).

[21] *Takeda Chem. Indus., Inc. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

130. ACTO*plus* met quickly grew to become one of Takeda's most profitable drugs. (By 2012, the product delivered more than $413 million in annual sales to Takeda).

G. The first generic ACTO*plus* met generic application.

131. On or about March 5, 2008, Mylan filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTO*plus* met. The Mylan ANDA, which was assigned ANDA No. 090406, contained a Paragraph IV certification as to the '584 Patent and the ACTO*plus* met Method-of-Use Patents.

132. By letter dated June 23, 2008, Mylan notified Takeda that Mylan had filed ANDA No. 090406, seeking to manufacture, market, and sell a generic version of ACTO*plus* met, and that the ANDA contained a Paragraph IV certification with respect to the '584 Patent and the ACTO*plus* met Method-of-Use Patents. Mylan was the first ANDA filer to submit a substantially complete ANDA with a Paragraph IV certification to market generic ACTO*plus* met.

133. On August 5, 2008, Takeda filed suit in the United States District Court for the Southern District of New York, *Takeda Pharmaceutical Co. Ltd., et al. v. Mylan Laboratories Inc., et al.*, Civil Action No. 1:08-cv-06999-DLC (S.D.N.Y.), alleging that Mylan's ANDA for generic ACTO*plus* met directly infringed, intentionally induced infringement, and/or contributed to the infringement of the '584 Patent and two of the three ACTO*plus* met Method-of-Use Patents.

134. Takeda filed the patent infringement case against Mylan without regard to the merits of the case. Simply by filing the lawsuit, Takeda obtained the automatic exclusion of Mylan from the market for thirty months and the ability to create a 180-day exclusivity bottleneck.

135. During the litigation, Mylan conducted discovery supporting a host of defenses focusing on the: (i) enforceability of the '584 Patent and the asserted ACTO*plus* met Method-of-Use Patents: (ii) validity of the '584 Patent and the asserted ACTO*plus* met Method-of-Use Patents: and (iii) strength of Takeda's indirect and contributory patent infringement allegations.

136. To prevent generic entry using just the strength of its patents, Takeda would have had to defeat Mylan's arguments regarding direct and indirect infringement. Instead, Takeda would later decide to protect its supracompetitive profits by paying Mylan to withdraw its defenses to the patents and delay introducing generic ACTO*plus* met.

H. The Teva generic ACTO*plus* met application

137. In late 2008 or early 2009, Teva filed an ANDA seeking FDA approval to manufacture, market, and sell generic ACTO*plus* met. The Teva ANDA, which was assigned ANDA No. 091155, contained a Paragraph IV certification as to the '584 Patent and the ACTO*plus* met Method-of-Use Patents.

138. By letter dated April 14, 2009, Teva notified Takeda that Teva had filed ANDA No. 091155, seeking to manufacture, market and sell generic versions of ACTO*plus* met and that the ANDA contained a Paragraph IV certification as to the '584 Patent and the ACTO*plus* met Method-of-Use Patents.

139. On May 18, 2009, Takeda filed suit against Teva in the United States District Court for the Southern District of New York, *Takeda Pharmaceutical Co. Ltd., et al. v. Teva Pharmaceutical Industries, Ltd., et al.*, Civil Action No. 1:09-cv-04665-DLC (S.D.N.Y.), alleging that Teva's ANDA for generic ACTO*plus* met directly infringed, intentionally induced infringement, and/or contributed to the infringement of the '584 Patent and two of the three ACTO*plus* met Method-of-Use Patents. In addition to these allegations regarding ACTO*plus*

met, Takeda also alleged that ANDA No. 077210, Teva's ANDA for ACTOS, intentionally induced infringement of the '584 Patent, the '404 Patent, and five of the ACTOS Method-of-Use Patents. Takeda filed the lawsuit without regard to its merits. In July 2009, Takeda's lawsuit against Teva was consolidated with the Takeda lawsuits against Mylan, Ranbaxy and Actavis.

I. Other generic manufacturers file ANDAs for generic ACTOS and generic ACTO*plus* met.

140. While the Takeda litigation against Mylan, Actavis, Ranbaxy and Teva regarding their ANDAs for ACTOS continued, other generics filed ANDAs for generic ACTOS that contained Paragraph IV certifications as to some or all of the Orange Book-listed patents for ACTOS. These generics notified Takeda of their respective ANDAs and the Paragraph IV certifications contained therein, and Takeda filed suit against each of these generics, alleging infringement of the '584 Patent, the '404 Patent and certain of the ACTOS Method-of-Use Patents:

Generic	ANDA No.	Date Sued
Sandoz, Inc.	078670	May 16, 2007
Torrent Pharmaceuticals Ltd.	091298	July 22, 2009
Aurobindo Pharma Ltd.	200268	January 13, 2010
Dr. Reddy's Laboratories Ltd.	078383	May 20, 2010
Wockhardt Ltd.	078038	July 28, 2010
Synthon Pharmaceuticals, Inc.	078472	September 8, 2010
Zydus Pharmaceuticals USA, Inc.	202456	January 14, 2011
Apotex, Inc.	202502	March 4, 2011
Macleods Pharmaceuticals Ltd.	202467	May 6, 2011
Accord Healthcare, Inc.	200044	September 12, 2011
Hetero Drugs Ltd.	293467	November 16, 2011

141. Likewise, after Mylan and Teva filed their ANDAs for generic ACTO*plus* met, additional ANDAs for generic ACTO*plus* met were filed by Sandoz, Inc. (ANDA 091273) and Aurobindo Pharma Ltd. (ANDA No. 200823) containing Paragraph IV certifications as to the Orange Book-listed patents for ACTO*plus* met. Takeda filed suit against Sandoz on June 3, 2009 and against Aurobindo on February 18, 2010.

J. Takeda wrongfully maintains its '584 and '404 Orange Book listings for ACTOS.

142. Since the time that Takeda had listed the '584 Patent and the '404 Patent in the Orange Book back in October 1999 and January 2002, Takeda wrongfully used those listings over the years, and it reiterated untruthfully the position that the patents cover generic ACTOS products.

143. For example, Takeda had used the wrongful listings to force Paragraph IV certifications by the first wave generic filers for generic ACTOS, had filed lawsuits against the first wave filers alleging infringement of the '584 Patent and the '404 Patent for generic ACTOS products not covered by those patents, and had forced Teva to make in some way (it chose a Section viii approach) a response to those listings.

144. On or about January 22, 2010 (and continuing its conduct of using the wrongful listings to gain anticompetitive advantage), Takeda responded to a citizen petition submitted to the FDA by Sandoz, another generic drug manufacturer that had filed an ANDA for generic ACTOS. Teva asserted that Takeda had improperly caused the FDA to list the '584 Patent and '404 Patent in the Orange Book as drug product patents for ACTOS. In its Comment to the Citizens Petition, dated January 22, 2010, Takeda "confirm[ed] for FDA the listing of [the '584 Patent and '404 Patent] under the terms described in Takeda's original patent submissions."

Takeda further acknowledged that it "characterized them for FDA in the appropriate patent declarations as containing both 'Drug product' and 'Method of use' claims," and that "[s]ince the original submission of these patents to FDA, Takeda has continued to certify to the applicability of the patents to ACTOS under the original declarations…."

145. In a ruling on the citizen petition, dated March 15, 2010, the FDA confirmed that Takeda's original patent information had indeed "stated that the patents claimed both the drug product and a method of use." The FDA further concluded that "[i]n keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA." The FDA specifically noted that Takeda's January 22, 2010 comment to the citizen petition had "reconfirm[ed]" the original listing. Moreover, "FDA's role in listing patents and patent information in the Orange Book is ministerial," and "FDA relies on the NDA sponsors to provide an accurate patent submission."

146. The FDA concluded that, because Takeda had submitted patent information describing the '584 Patent and '404 Patent as claiming the ACTOS drug product, all ANDA filers seeking approval to market generic ACTOS before the expiration of the patents were required to submit Paragraph IV certifications, rather than Section viii statements, with respect to them. The requirement that Teva and all ANDA filers submit Paragraph IV certification – and thereby become subject to the first-filer's 180-exclusivity – resulted from Takeda's description of the '584 Patent and '404 Patent as drug product patents claiming ACTOS. The FDA concluded that, "it is the patent declaration submitted by the NDA holder and any subsequent amendments or supplements to that declaration that controls FDA's listing of patents and patent information. In keeping with our practice of relying solely on the NDA sponsor's patent

declaration describing relevant patent claims in Orange Book-listed patents, FDA will rely on Takeda's patent declarations submitted to FDA."

147. The Teva lawsuit was scheduled for trial beginning in June 2010, in time for Teva to obtain a favorable ruling before the expiration of the ACTOS '777 Patent in January 2011.

148. On March 15, 2010, while the lawsuit was pending, the FDA issued its decision on the Citizens Petition discussed in detail above, concluding that, in its purely ministerial role, the FDA would rely solely on Takeda's patent information. Because Takeda submitted patent information stating that the '584 Patent and '404 Patent claimed both the "drug product" ACTOS and its "method of use," the FDA concluded that it could not approve any ANDA that did not include a Paragraph IV certification as to the '584 Patent and '404 Patent, which Teva's ANDA for ACTOS did not include.

K. The dynamics of competition in early 2010.

149. In early 2010, Takeda, the first wave generics (Mylan, Actavis and Ranbaxy), and Teva each faced competitive pressures produced by our free market system, the structure of competition established by the Hatch-Waxman Act, and laws fostering automatic substitution of brand drugs by FDA-approved generic equivalents upon expiry of valid patents.

150. As to Takeda, it was enjoying a $3 billion a year franchise for ACTOS and ACTO*plus* met, but time was quickly running out. As to ACTOS, it faced generic challenges not only from the first wave generics and Teva, but also from over a half dozen other generics that were actively seeking FDA approval for generic ACTOS. Takeda's '777 patent would expire on January 17, 2011, and Takeda was likely to lose on its assertion of infringement against generic ACTOS makers relating to its other patents. Takeda was simply likely to lose the ACTOS infringement actions it then had pending. As to ACTO*plus* met, Takeda similarly faced powerful

Mylan and Teva challenges to its assertions of patent exclusivity, and was embroiled in litigation for which it had little likelihood of success. The consequences of a loss would mean the absolute loss of the franchise. Takeda's *lawful* settlement options were to resolve each lawsuit separately with each generic maker, doing so based on the (limited) merits the applicable lawsuit against that maker, without paying off the generic, and without orchestrating future entry dates (or prices) amongst itself and its various generic competitors.

151. For Mylan and its ACTOS generic ANDA, Mylan faced competition on numerous fronts. First, Mylan faced competition from the two other makers (Actavis and Ranbaxy) with whom it shared the first-to-file 180-day exclusivity for ACTOS. Since both of those companies had pending ANDAs, either one or the other might seek to obtain FDA approval and launch its product as close to January 17, 2011 as possible; once it did so, the 180-day exclusivity period would be triggered, and Mylan would need to have obtained its FDA approval to launch at that time (or earlier, if it could beat to market the companies with whom it shared exclusivity). Second, Mylan faced competition from Teva (the largest of generic makers) which at the time was pursuing a separate, rapid regulatory approach (the Section viii approach) to gain FDA approval to launch generic ACTOS. If Teva were able to get a favorable ruling (from the FDA or a court) on its Section viii position during 2010 or so (a highly likely prospect given the clear lack of coverage of the '584 and '404 patents to ACTOS), then Teva would be able to immediately enter the market, and Mylan would lose the substantial economic benefit from its 180-day exclusivity. Third, Mylan faced likely competition from Takeda because, upon generic entry and regardless of the 180-day exclusivity, Takeda would be able to launch an authorized generic product at any time, and thereby further reduce Mylan's market share and force further price pressure downwards. Fourth, Mylan faced competition from numerous other generic

companies because, upon lapse of the 180-day exclusivity, the ACTOS market would likely become inundated with multiple generic makers such that the entire ACTOS market would become wholly commoditized.

152. As for Mylan's ACTO*plus* met generic ANDA, while Mylan had the sole first-to-file exclusivity for ACTO*plus* met, it nevertheless faced significant competitive pressures. Mylan knew that upon generic entry Takeda would be able to launch an independent authorized generic. Mylan also knew that Teva was actively pursuing a generic ACTO*plus* met ANDA, and that Teva's legal position in the ACTO*plus* met infringement suit was so strong that there was a likely prospect that Teva would break the bottleneck of Mylan's sole exclusivity (with enormous loss to Mylan). And Mylan knew that upon lapse of the 180-day exclusivity the ACTO*plus* met market would likely become inundated with multiple generic makers.

153. Mylan's *lawful* settlement option was to resolve the ACTOS and ACTO*plus* met lawsuits with Takeda, but to do so separately from its generic competitors, without accepting a payoff from Takeda, and without colluding with Takeda and the other two first wave generics to set future entry dates (or prices). Acting in its own, independent economic interest (and without colluding with its competitors), Mylan would seek an agreed entry date on or about January 17, 2011; after all, if Mylan accepted any later date, it would be exposed to the potential that one of its competitors would obtain an earlier entry date (by settlement or litigation). As a result, it was in Mylan's own, independent economic interest (without colluding with its competitors) to seek an agreement for entry on or about January 17, 2011. Absent that, Mylan would press litigation, and likely win it.

154. As for Actavis and Ranbaxy and their ACTOS ANDAs, they were in a similar position as Mylan. Each faced competition from the other generics with whom they shared 180-

day exclusivity, faced the threats of Takeda's authorized generic, and faced Teva's early entry generic threat (through the Section viii approach on ACTOS), and faced the prospect of complete commoditization upon expiration of the 180-day exclusivity (or Teva's success with its Section viii approach). Unlike Mylan, however, neither Actavis nor Ranbaxy had begun the process to address patent issues relating to ACTO*plus* met. Acting in their own, independent economic interest (and without colluding with their competitors), Actavis and Ranbaxy would each (separately) seek from Takeda an agreed entry date on or about January 17, 2011; were either to agree to any later date, it would be exposed to the potential that one of its competitors would obtain an earlier entry date (by settlement or litigation). Absent an agreement for entry on or about January 17, 2011, they would press litigation, and win it.

155. And finally, Teva faced significant competitive pressures, but also had some advantages. As to Teva's ACTOS ANDA, while Teva knew that other generic companies had a shared 180-day exclusivity, it also knew it was pursuing generic ACTOS FDA approval through a Section viii approach, and that doing so was likely to avoid the lengthy tedium of the Paragraph IV certification process. And since Teva's approach would vitiate the 180-day stranglehold, Teva had strong economic incentive to pursue that approach and gain a period of *de facto* exclusivity for itself. As to Teva's ACTO*plus* met ANDA, Teva knew that Mylan held a sole 180-day exclusivity, but Teva also knew that it had strong legal arguments against Takeda's infringement claims such that it might break the bottleneck imposed by Mylan's exclusivity. In short, in early 2010 Teva was very much in a spoiler role, asserting significant pressure to gain timely generic entry.

L. Takeda orchestrates a group deal with the first wave generics, Mylan, Ranbaxy, and Actavis.

156. In late February and early March of 2010, Takeda orchestrated a group deal with Mylan, Actavis and Ranbaxy in order to delay generic entry. Rather than pursue their independent economic interests, all four companies agreed to an overarching scheme to restrain the competitive pressures they faced. They combined their efforts, and reached an overall agreement to (i) allocate the markets for ACTOS and ACTO*plus* met, (ii) set uniform agreed entry dates between themselves, (iii) delay the entry of generics for both products, (iv) collude to protect their 180-day exclusivity the first wave generics had obtained through Takeda's wrongful Orange Book listings, and (v) restrain Teva's effort to gain timely entry of generic ACTOS. The overall agreement was in reality a single deal between all four companies, but they memorialized the agreement in separate written agreements between the companies, though the documents contained nearly identical entry date provisions and disincentives for independent actions. In purpose and effect, the first wave generics – Mylan, Actavis and Ranbaxy – joined Takeda's long-term scheme to delay generic competition. The overall, single agreement is herein called the Exclusion Payment Agreement.

157. On or about March 15, 2010, Takeda entered into the Exclusion Payment Agreement with each of Mylan, Actavis, and Ranbaxy. For ACTOS, the Exclusion Payment Agreement required Takeda to immediately dismiss its patent infringement litigation against Mylan, Actavis, and Ranbaxy, and for Mylan, Actavis, and Ranbaxy to, in turn, drop their challenges to the Takeda patents. Mylan, Ranbaxy, and Actavis also agreed to delay launching their generic ACTOS products until August 17, 2012, or earlier under certain circumstances. For ACTO*plus* met, under the terms of the agreement Mylan agreed to drop its challenge to Takeda's

patents. Mylan also agreed to stay out of the market with generic ACTO*plus* met until December 14, 2012, or August 17, 2012 if Takeda's sales of ACTO*plus* met dipped below a certain threshold (which they did).

158. As the *quid pro quo* for Mylan's, Actavis' and Ranbaxy's agreements to drop their challenges to the patents and delay entry for both products, Takeda agreed to pay Mylan, Ranbaxy, and Actavis substantial sums. Takeda's payments to the first wave generic defendants under the Exclusion Payment Agreement took several forms.

159. *First*, Takeda agreed that in the event any other generic ACTOS product entered the market before August 17, 2012, the licensed entry dates for Mylan, Ranbaxy, and Actavis would be moved up correspondingly. The purpose and effect of these acceleration clauses was to deter any other generic drug manufacturer from entering the market before then. In particular, Takeda, Mylan, Ranbaxy, and Actavis specifically intended these clauses to create a major disincentive for Teva to continue its effort to gain timely generic entry through its Section viii approach; the agreement also sought to incentivize Teva to join the agreement to delay generic ACTOS entry until August 17, 2012. Eliminating the potential for Teva to enter the market before Mylan, Ranbaxy, and Actavis was of enormous benefit to the generics – worth hundreds of millions of dollars – and was compensation that they could not have obtained even if they had won the ACTOS patent litigation. The acceleration clauses were large and unjustified payments from Takeda to each of Mylan, Ranbaxy, and Actavis.

160. *Second*, Takeda agreed that, in the event that any other generic ACTO*plus* met entered the market before the time specified for Mylan to enter, the licensed entry date for Mylan would be moved up correspondingly. The purpose and effect of this acceleration clause was to

deter any other generic drug manufacturer from entering before Mylan's scheduled entry date – it sought to lock in Mylan's 180-day exclusivity for ACTO*plus* met.

161. *Third*, Takeda agreed that the terms on which Takeda and Mylan agreed to settle the ACTOS lawsuit were contingent on the terms on which those parties agreed to settle the ACTO*plus* met lawsuit, and *vice versa*. The payments and provisions were designed to, and did in fact, deter Teva from undermining the Exclusion Payment Agreement that Takeda and Mylan reached with respect to ACTOS. In exchange for all of the payments that Mylan received with respect to both lawsuits, including those successfully designed to deter Teva from undermining the ACTOS anticompetitive scheme, Mylan agreed to delay entry of generic ACTO*plus* met.

162. *Fourth*, Takeda agreed to give Ranbaxy two "sweetheart" deals. For the ACTOS sweetheart deal, Takeda gave Ranbaxy the right to enter with an authorized generic ACTOS under distribution terms that provided Ranbaxy with net revenue far in excess of fair market terms. For the ACTOplus met sweetheart deal, Ranbaxy had not filed an ANDA seeking FDA approval to market ACTO*plus* met and had not made any certifications that Takeda's patents on ACTO*plus* met were invalid or would not be infringed by a generic version of ACTO*plus* met. But in order to induce Ranbaxy to delay entry with its generic ACTOS, Takeda gave Ranbaxy a license for ACTO*plus* met that was of substantial value to Ranbaxy and was compensation that it could not have been obtained even if it had won the ACTOS patent litigation. The license for ACTO*plus* met was a large and unjustified payment from Takeda to Ranbaxy.

163. *Fifth*, Takeda gave Actavis a "sweetheart" deal. Actavis had not filed an ANDA seeking FDA approval to market ACTO*plus* met and had not made any certifications that Takeda's patents on ACTO*plus* met were invalid or would not be infringed by a generic version of ACTO*plus* met. But in order to induce Actavis to delay entry with its generic ACTOS,

Takeda gave Actavis a license for ACTO*plus* met that was of substantial value to Actavis and was compensation that it could not have been obtained even if it had won the ACTOS patent litigation. The license for ACTO*plus* met was a large and unjustified payment from Takeda to Ranbaxy.

164. All of these benefits had substantial value to Mylan, Ranbaxy, and Actavis, and are compensation that they could not have otherwise obtained even if they had litigated and won the various patent cases. These payments caused Mylan, Ranbaxy, and Actavis to stay out of the markets for ACTOS and ACTO*plus* met longer than they otherwise would have. And Takeda made these payments to Mylan, Ranbaxy, and Actavis in exchange for their agreeing to delay entry with their generic ACTOS and ACTO*plus* met products. In short, Takeda made large, unjustified payments to Mylan, Ranbaxy, and Actavis to delay their entry into the market with generic ACTOS and ACTO*plus* met.

M. The intended restrictions on competition from the Exclusion Payment Agreement.

165. The Exclusion Payment Agreement was intended to restriction competition in the markets for ACTOS and ACTO*plus* met in multiple ways, and the restrictions impacted each competitive threat that previously existed.

166. *First*, the arrangement restricted the competition that previously existed between Mylan, Ranbaxy, and Actavis, each of which was ostensibly supposed to be competing with the others to gain the earliest possible entry date. Since they orchestrated a mutually agreed entry date amongst themselves, none no longer faced the threat of one or both of the two others beating them to the market, and thus to that extent the motivation of each was to obtain an earlier entry date than the others was eliminated.

167. *Second*, the arrangement restricted the competition by significantly reducing the incentives for Teva to continue its Section viii efforts to gain timely generic entry. Because Takeda had arranged that all three first wave generic filers could enter the market if Teva succeeded in its Section viii approach to timely generic entry, Teva knew that it no longer had a reasonable prospect of gaining timely entry with *de facto* exclusivity for some period of time; instead, the other generics could also pounce into the market at that time too.

168. *Third*, the arrangement restricted competition by helping to maintain the 180-day exclusivity held by Mylan, Ranbaxy and Actavis for ACTOS. Recall that these generics gained this exclusivity solely because Takeda had wrongfully listed the '584 and '404 patents in the Orange Book. If Teva (or any other company) were able to get a court declaration that the listing of those patents was unlawful, then the 180-day exclusivities that rested on those listings were be eliminated. Disincentives to pursue such a court order had the intended effect of diminishing the risks of elimination of the 180-day exclusivities.

169. *Fourth*, the arrangement restricted the competition by prolonging the bottleneck presented by the 180-day exclusivity held by the first wave generics for ACTOS. Because each of the first wave generics had filed their ANDAs for ACTOS before enactment of the 2003 MMA amendments, under the law before the amendments the first generic manufacturer(s) to file an ANDA with a Paragraph IV certification could not forfeit the 180-day exclusivity by failing to market the drug. Therefore, the first generic drug manufacturer applicant could agree with the branded drug manufacturer to delay marketing the generic, while still safely retaining the 180-day exclusivity. By thus "parking" its 180-day exclusivity, the first filer could create a "bottleneck" that precluded *all* generic drug manufacturers from entering the market until 180 days after the first filer entered.

170. The intended effect of Takeda's Exclusion Payment Agreements with each of Mylan, Ranbaxy, and Actavis was to delay entry into the market by them and all subsequent ANDA filers. Other generic drug manufacturer competitors had notified Takeda that they had filed ANDAs for generic of ACTOS that contained a Paragraph IV certification as to the '584 Patent and the '404 Patent. In each case, Takeda filed a patent infringement suit against the generic manufacturer alleging that the manufacturer's generic ACTOS product would directly infringe the '584 Patent and '404 Patent, and indirectly infringe certain of the ACTOS Method-of-Use Patents. Takeda filed the patent infringement cases against these potential generic drug manufacturer competitors without regard to the merits of the cases. Simply by filing the cases, Takeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

171. In light of the prolonged bottleneck created by the Exclusion Payment Agreement with Mylan, Ranbaxy, and Actavis, the later generic filers each were, as a practical economic matter, required to fall in line with the protracted, delayed entry date for ACTOS generics.

172. *Fifth*, the arrangement restricted the competition by prolonging the bottleneck presented by the 180-day exclusivity held by Mylan for ACTO*plus* met. As the first ANDA filer to submit a substantially complete ANDA with a Paragraph IV certification with respect to ACTO*plus* met, Mylan secured the Hatch-Waxman 180-day exclusivity. Although Congress had sought in the 2003 MMA amendments to reduce the incidence of drug manufacturers entering into Exclusion Payment Agreements to create "bottlenecks," unscrupulous manufacturers could still structure such agreements to create very substantial obstacles to entry by later-filing generics. Under the MMA, the generic first-filer retains its 180-day exclusivity if it enters into a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. In order to trigger

forfeiture and gain access to the market, subsequent ANDA applicants are then forced to obtain a judgment that all patents for which the first filing generic manufacturer filed Paragraph IV certifications are invalid or not infringed.

173. Takeda and Mylan in fact "gamed the system" in just this way, entering into a voluntary dismissal without the requisite findings that would have resulted in a forfeiture of Mylan's 180-day exclusivity. Consequently, the Exclusion Payment Agreement constructed very substantial barriers to entry by later-filing generic drug manufacturers.

174. *Sixth* but by no means last, the arrangement restricted the competition by delaying the entry dates for generic ACTOS and ACTOplus met, thereby extending the $3 billion a year franchise for about a year and a half.

N. Teva moves to add a counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) against Takeda.

175. With the execution of the Exclusion Payment Agreement for ACTOS and ACTO*plus* met in March 2010, and the consequent prolonged bottlenecks that also delayed entry by later-filing generic drug manufacturers, Takeda and its generic co-conspirators -- Mylan, Ranbaxy, and Actavis -- had tamed almost all of the threats that could unleash competitive rivalry and bring lower prices to consumers before the dates specified in the Exclusion Payment Agreements. But one significant threat remained, so Takeda and its generic coconspirators worked together to neutralize the potential competitor and bring it into the conspirators' non-competition pact.

176. On March 30, 2010, Teva countered this development by filing a motion to amend its answer to add a counterclaim against Takeda based on Takeda's improper submission of patent information for the '584 Patent and the '404 Patent describing the patents as drug

product patents claiming ACTOS. As Teva stated in its proposed Amended Answer, Affirmative Defenses and Counterclaim:

> As a direct and proximate cause of Takeda's submission of false, misleading, and/or incorrect patent information to FDA, . . . Teva is likely to suffer significant harm in the form of a substantial delay to the approval of Teva's Actos® ANDA. If Teva is required to file a Paragraph IV certification due to the incorrect listings of the '584 and the '404 patents in the Orange Book, Takeda might file a new lawsuit triggering a 30-month stay of approval of Teva's Actos® ANDA. In addition, whether or not Takeda files such a lawsuit, Teva's ANDA could not be approved until after the expiration of any 180-day exclusivity period to which the first-filer(s) of ANDA(s) for generic versions of Actos® may be entitled. Either way, final approval of Teva's Actos® ANDA likely will be delayed substantially beyond the January 2011 date (the expiration of the '777 patent) on which Teva's ANDA otherwise likely would be approved.

Teva sought an order pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) requiring Takeda "to correct or delete the patent information Takeda submitted to FDA in reference to NDA 21-073 concerning the drug product claims in the '584 and '404 patent[s] by submitting information to FDA clarifying that the drug product claims in those patents do not claim the drug product approved by NDA 21-073 and that those drug product claims do not form a basis upon which Takeda could reasonably assert a claim of patent infringement against an ANDA applicant for a generic version of Actos®." Had Teva succeeded on its counterclaim, Teva would not have been subject to the 180-day bottleneck that Takeda and Mylan, Ranbaxy, and Actavis constructed and extended with their Exclusion Payment Agreements, and Teva could have entered the market with generic ACTOS as early as January 17, 2011.

177. Shortly after Teva filed its motion to add the counterclaim based on Takeda's improper listing of patent information for the '584 Patent and '404 Patent, Takeda and Teva

began serious settlement negotiations. At the parties' joint request, on April 14, 2010, the court adjourned the June 2010 trial date.

178. During the settlement negotiations, Takeda used "carrots and sticks." The sticks included the acceleration clauses that Takeda and its other generic drug manufacturer co-conspirators had incorporated in the Exclusion Payment Agreements for both ACTOS and ACTO*plus* met. The acceleration clauses in the Exclusion Payment Agreement with each of Mylan, Ranbaxy, and Actavis provided that, in the event that any other manufacturer succeeded in entering the market with a generic ACTOS product before August 17, 2012, the licensed entry date for Mylan, Ranbaxy, and Actavis would be accelerated to the earlier date. The acceleration clauses thus ensured that no other generic drug manufacturer, no matter how much time and resources it spent in its litigation against Takeda, and no matter how successful the generic drug manufacturer was in the litigation, could enter the market before Mylan, Ranbaxy, and Actavis. The Exclusion Payment Agreement between Takeda and Mylan with respect to ACTO*plus* met had a similar acceleration clause.

179. The purpose and effect of the acceleration clauses was to dramatically reduce Teva's incentive to try to enter the market before Mylan, Ranbaxy, and Actavis. Absent the acceleration clauses, Teva had a significant possibility of entering the market with generic ACTOS before August 17, 2012, thereby enjoying a substantial period as the only generic ACTOS product on the market. By eliminating this possibility, the acceleration clauses resulted in later generic entry in at least two ways: (i) the clauses directly reduced Teva's incentive to continue litigating in order to gain entry before Mylan, Ranbaxy, and Actavis, and (ii) by eliminating the threat to Mylan's, Ranbaxy's, and Actavis' 180-day exclusivity, the clauses compensated them for delaying their entry into the market. In short, the acceleration clauses

eliminated Teva's competitive threat to Mylan, Ranbaxy, and Actavis, in return for which they agreed to later entry.

180. While keeping most of the terms in their Exclusion Payment Agreements confidential, Mylan, Ranbaxy, and Actavis agreed that Takeda could advise Teva of the existence of the acceleration clauses. The purpose and effect of the disclosure was to dissuade Teva from entering the market before August 17, 2012.

181. The "carrots" that Takeda offered to Teva to give up the patent fight were the payments that the parties included in their unlawful Exclusion Payment Agreement, discussed below.

O. Takeda and Teva Execute an Exclusion Payment Agreement to Delay Generic ACTOS and Generic ACTO*plus* met.

182. On December 22, 2010, Takeda and Teva entered into an Exclusion Payment Agreement pursuant to which Teva agreed to: (i) drop its challenges to Takeda's patents with respect to both ACTOS and ACTO*plus* met; (ii) drop its counterclaim asserting that Takeda had submitted false and misleading patent information as to the '584 Patent and '404 Patent; and (iii) stay out of the market with generic ACTOS until August 17, 2012, and stay out of the market with generic ACTO*plus* met until the date on which Mylan entered the market.

183. As the *quid pro quo* for Teva's agreement to significantly delay competition, Takeda agreed to pay Teva substantial compensation. Takeda's payments to Teva under the Exclusion Payment Agreement took at least the following forms.

184. *First*, Takeda agreed that neither it nor its affiliates would launch an authorized generic version of ACTOS during Teva's first 180 days of marketing. This non-competition pledge provided substantial compensation to Teva, which could expect higher unit sales, at a

higher price, absent Takeda's authorized generic version of ACTOS in the market. The non-competition pledge was worth tens of millions of dollars and constitutes compensation to Teva.

185. *Second*, Takeda agreed that, with the exception of the licenses to which it had already agreed with Mylan, Ranbaxy, and Actavis, Takeda would not grant any other generic drug manufacturer a license to enter the market with generic ACTOS until 180 days after Teva entered the market. The no-license pledge was worth tens of millions of dollars and constitutes compensation to Teva.

186. *Third*, Takeda agreed that, in the event any other generic ACTOS entered the market before the time specified for Teva to enter the market, the licensed entry date for Teva would be accelerated correspondingly. As discussed in detail above, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

187. *Fourth*, Takeda granted Teva a license to market generic ACTO*plus* met under Takeda's NDA beginning on the date that Mylan first entered the market with its generic ACTO*plus* met. Anticipating that they would succeed in enticing Teva to join the non-competition pact, Takeda and Mylan had agreed that Takeda could provide such a license to Teva with respect to ACTO*plus* met, and Takeda and Mylan had included such a provision in their earlier agreement.

188. *Fifth*, Takeda agreed that neither it nor its affiliates would launch an authorized generic version of ACTO*plus* met during Teva's first 180 days of marketing. This provided substantial compensation to Teva, which could expect higher unit sales, at a higher price, absent Takeda's authorized generic version of ACTO*plus* met in the market. The no-competition pledge was worth tens of millions of dollars and constitutes compensation to Teva.

189. *Sixth*, Takeda agreed that, with the exception of the licenses already granted to Mylan, Takeda would not grant any other generic drug manufacturer a license to enter the market with generic ACTO*plus* met until 180 days after Teva entered the market. The no-license pledge was worth tens of millions of dollars and constitutes compensation to Teva.

190. *Seventh*, Takeda agreed that, in the event any other generic ACTO*plus* met entered the market before the time specified for Teva to enter the market, the licensed entry date for Teva would be accelerated correspondingly. As discussed in detail above, the purpose and effect of this acceleration clause was to deter any other generic drug manufacturer from entering before Teva's scheduled entry date.

191. All of these benefits had substantial value to Teva, and are compensation that it could not have obtained even if it had litigated and won the patent case. These payments caused Teva to stay out of the market longer than it otherwise would have done. And Takeda made these payments to Teva in exchange for its agreeing to delay entry with its generic ACTOS and ACTO*plus* met products. In short, Takeda made large, unjustified payments to Teva to delay entry into the markets.

P. The other generics fall in line.

192. Teva, Sandoz and Aurobindo had notified Takeda that they had filed ANDAs for generic ACTO*plus* met that contained a Paragraph IV certification with respect to the '584 Patent and the ACTO*plus* met Method-of-Use Patents. In each case, Takeda filed a patent infringement suit alleging the generic ACTO*plus* met product in question would directly infringe the '584 Patent and indirectly infringe certain of the ACTO*plus* met Method-of-Use patents. Takeda filed these patent infringement cases against the potential generic drug manufacturer

competitors without regard to the merits of the cases. Simply by filing the lawsuits, Takeda obtained automatic exclusion of these ANDA filers from the market for thirty months.

193. In light of the prolonged bottleneck created by the Exclusion Payment Agreement with Mylan and others, all of these subsequent ANDA filers entered into joint stipulations dismissing their patent cases with Takeda. Each of these potential competitors agreed to delay entry into the market until 180 days after Mylan and others entered. Absent the prolonged bottlenecks created by the Exclusion Payment Agreement, many or most of these later ANDA filers would have entered the market much sooner than they did.

Q. The 2011 through 2014 acts in furtherance of the Exclusion Payment Agreement

194. From late January of 2011 (when they otherwise could have entered the ACTOS and ACTO*plus* met markets) until late August of 2012, each of Mylan, Actavis, Ranbaxy and Teva abided their agreements with Takeda – they did not launch generic products into those markets, and undertook whatever activities were required (with, for example, the FDA) so as to make sure they kept the promise to Takeda to stay out until late August of 2012. Meanwhile, Takeda kept its promise and did not grant any licenses to other companies, all in accordance with its promises in the Exclusion Payment Agreement.

195. In or about the summer of 2012, Takeda worked closely with two of its co-conspirators – Teva and Ranbaxy – in order to implement the sweetheart authorized generic distributorships Takeda had granted them for ACTOS. In or about late August of 2012, Takeda and Teva, and also Takeda and Ranbaxy, launched authorized generics of ACTOS. Neither Teva nor Ranbaxy launched their own, ANDA-approved generic at this time. Takeda also kept its commitment not to launch an independent (market rate) authorized generic.

196. For at least two years, and certainly into 2014, Takeda continued to pay both Teva and Ranbaxy through the sweetheart, authorized distributorships. The distributorship was so valuable to Teva that Teva did not press for approval of its own ANDA-approved generic for many, many months.

197. In or about the summer of 2012, Takeda also worked closely with Teva in order to implement the sweetheart authorized generic distributorship Takeda had granted it for ACTO*plus* met. In or about late August of 2012, Takeda and Teva launched an authorized generic of ACTO*plus* met. Teva did not launch its own, ANDA-approved generic at this time. Takeda also kept its commitment not to launch an independent (market rate) authorized generic of ACTO*plus* met.

198. For at least two years, and certainly into 2014, Takeda continued to pay Teva through the sweetheart, ACTO*plus* met authorized distributorship. The distributorship was so valuable to Teva that Teva did not press for approval of its own ANDA-approved generic for many, many months.

199. The Exclusion Payment Agreement had its intended impact on the ACTOS market. First, generics were delayed from late January until late August of 2012, during which monthly sales were about $200 million. In effect, the agreement protected Takeda from generic competition during which retails sales totaled about $3.6 billion. Second, the agreement's plan to protect high sales for a few generics during the first six months of entry worked. During this period, only the conspiring generics were able to get into the ACTOS market, and they shared sales of about a $100 million per month market; upon the entry of other generics, the market size would drop to about $60 million per month. Third, the agreement's plan to keep prices relatively high period the first six months of exclusivity also worked; while in the first six months the

average retail price was in the $240 to $250 per prescription range, post-exclusivity the average retail price dropped to about $165 per prescription or lower. A competitive market for ACTOS would have yielded about $60 million a month shared amongst many competitors; it would not have been the $200 million a month Takeda enjoyed by itself for 18 months, nor the $100 million a month the co-conspiring oligopoly of generics enjoyed for the first six months of (unlawfully produced) exclusivity.[22]

200. The Exclusion Payment Agreement also had its intended impact on the ACTO*plus* met market. First, generics were delayed from late January until late August of 2012, during which monthly sales were about $30 million. In effect, the agreement protected Takeda from generic competition during which retails sales totaled about $540 million. Second, the agreement's plan to protect high sales for a few generics during the first six months of entry worked. During this period, only Mylan and Teva (two of the conspiring generics) were able to get into the ACTO*plus* met market, and they shared sales of about a $17 million per month market; upon the entry of other generics, the market size would drop to about $14 million per month. Third, the agreement's plan to keep prices relatively high period the first six months of exclusivity also worked; while in the first six months the average retail price was in the $300 per prescription range, post-exclusivity the average retail price dropped to about $285 per prescription or lower.

[22] These numbers are, of course, pre-discovery and are based only on publicly available information. They will be refined, of course, during discovery.

VII. ANTICOMPETITIVE EFFECTS OF THE SCHEME AND AGREEMENTS

201. Defendants' conduct delayed and substantially diminished the sale of generic ACTOS and ACTO*plus* met in the United States. But for defendants' illegal conduct, generic drug manufacturers would have entered the market unimpeded and competed on the merits against ACTOS and ACTO*plus* met. Generic drug manufacturers of ACTOS would have been able to compete as early as January 17, 2011. Generic drug manufacturers of ACTO*plus* met would have been able to compete as early as February 25, 2011. Defendants' conduct unlawfully delayed and diminished the savings that purchasers of ACTOS and ACTO*plus* met and their generic equivalents would have garnered from unimpaired generic competition, with the anticompetitive effect of unlawfully maintaining supra-competitive prices for ACTOS and ACTO*plus* met.

202. Defendants' conduct harmed plaintiff and the direct purchaser class by depriving them of the most cost efficient means of distribution, *i.e.*, a marketplace in which brand and generic manufacturers make their decisions about challenging patents on the basis of the merits (or lack thereof) of the patent challenges, free from the influence of unlawful payments and market allocation arrangements. Contrary to the purpose of the Hatch-Waxman Act, defendants' anticompetitive conduct enabled them to: (i) delay the entry of less expensive generic versions of ACTOS and ACTO*plus* met in the United States; (ii) fix, raise, maintain, or stabilize the price of ACTOS and ACTO*plus* met; and (iii) permit Takeda to maintain a monopoly in the United States market for ACTOS, ACTO*plus* met and its generic equivalents.

203. As a direct and proximate result of defendants' unlawful conduct, plaintiff and the direct purchaser class have sustained (and will continue to sustain) substantial losses and damage

to their business and property in the form of overcharges they paid for ACTOS and ACTO*plus* met and their generic equivalents, the exact amount of which will be proven at trial. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as plaintiff and members of the class, would have paid less for these drugs by (a) receiving discounts on their remaining brand purchases of these drugs, (b) substituting purchases of less-expense generic versions for their purchases of more-expensive brand versions, and/or (c) purchasing the generic versions of these drugs at lower prices sooner.

VIII. CLASS ACTION ALLEGATIONS

204. Plaintiff, on behalf of itself and all direct purchaser class members, seeks damages, measured as overcharges, trebled, against defendants based on allegations of anticompetitive conduct in the market for ACTOS and ACTO*plus* met, and their AB-rated generic equivalents.

205. Plaintiff brings this action under FED. R. CIV. P. 23(a) and (b)(3), on behalf of itself and as the representative of a direct purchaser class defined as follows:

> All persons or entities in the United States and its territories who directly purchased ACTOS and/or its AB-rated generic equivalents in any form from January 17, 2011 through and including the date that the anticompetitive effects of defendants' unlawful conduct cease (the "ACTOS class period"); and
>
> All persons or entities in the United States and its territories who directly purchased ACTO*plus* met and/or its AB-rated generic equivalents in any form from February 25, 2011 through and including the date that the anticompetitive effects of defendants' unlawful conduct cease (the "ACTO*plus* met class period").

Excluded from the direct purchaser class are defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

206. Members of the direct purchaser class are so numerous that joinder is impracticable. Plaintiff believes that the class numbers in the many scores of entities. Further, the direct purchaser class is readily identifiable from information and records in defendants' possession.

207. Plaintiff's claims are typical of those of each of the members of the direct purchaser class. Plaintiff and each of the class members were damaged by the same wrongful conduct of defendants, *i.e.*, as a direct and proximate result of defendants' wrongful conduct, they paid artificially inflated prices for ACTOS and/or ACTO*plus* met and were deprived of the benefits of earlier and robust competition from cheaper generic versions of the products.

208. Plaintiff will fairly and adequately protect and represent the interests of the direct purchaser class. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the direct purchaser class members.

209. Plaintiff is represented by counsel with experience in prosecuting class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

210. Questions of law and fact common to the class members predominate over questions that may affect only individual class members, because defendants have acted on grounds generally applicable to the entire class, thereby making the recovery of overcharge damages with respect to the direct purchaser class as a whole appropriate. Such generally applicable conduct is inherent in defendants' wrongful conduct.

211. Questions of law and fact common to the direct purchaser class include, but are not limited to:

a. whether defendants conspired to willfully maintain and/or enhance Takeda's monopoly power over ACTOS and/or ACTO*plus* met, and their respective generic equivalents;

b. whether Takeda submitted improper patent information describing the '584 Patent and the '404 Patent as purported drug product patents covering ACTOS;

c. whether defendants conspired to suppress generic competition to ACTOS and/or ACTO*plus* met;

d. whether Takeda and Mylan, Teva, Ranbaxy and/or Actavis entered into unlawful agreements in restraint of trade;

e. whether, pursuant to such agreements in restraint of trade, Mylan, Teva, Ranbaxy, and/or Actavis agreed to delay their entry into the market with generic ACTOS;

f. whether, pursuant to such agreements in restraint of trade, Takeda paid Mylan, Teva, Ranbaxy, and/or Actavis;

g. whether Takeda's payments to Mylan, Teva, Ranbaxy, and Actavis were for a purpose other than delayed entry of generic ACTOS;

h. whether Takeda's payments to Mylan, Teva, Ranbaxy, and Actavis were necessary to yield a procompetitive benefit that is cognizable and non-pretextual;

i. whether the Exclusionary Payment Agreements are unlawful under the rule of reason by reason because of large and unjustified payments from Takeda to generic defendants ;

j. whether the Exclusionary Payment Agreements are *per se* unlawful because they restrict competition outside the exclusionary scope of Takeda's patents;

k. whether Takeda possessed market power or monopoly power over pioglitazone hydrochloride;

l. whether Takeda, Mylan, and/or Teva conspired to suppress generic competition to ACTO*plus* met;

m. whether Takeda, Mylan, and/or Teva entered into unlawful agreements in restraint of trade;

n. whether, pursuant to such agreements in restraint of trade, Mylan and/or Teva agreed to delay their entry into the market with generic ACTO*plus* met;

o. whether, pursuant to such agreements in restraint of trade, Takeda paid Mylan and/or Teva;

p. whether Takeda's payments to Mylan and/or Teva were for a purpose other than delayed entry of generic ACTO*plus* met;

q. whether Takeda's payments to Mylan and/or Teva were necessary to yield a procompetitive benefit that is cognizable and non-pretextual;

r. whether Takeda possessed market power or monopoly power over pioglitazone hydrochloride and metformin hydrochloride;

s. whether Takeda possessed market power in the relevant market(s);

t. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;

u. whether defendants' above-described conduct has substantially affected interstate and intrastate commerce;

v. whether, and to what extent, defendants' conduct caused antitrust injury (*i.e.*, overcharges) to plaintiff and class members; and

w. the quantum of aggregate overcharge damages to plaintiff and class members.

212. Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in the management of this action as a class action.

213. Plaintiff knows of no special difficulty that would be encountered in this action that would preclude its maintenance as a class action.

214. Certification of the class is appropriate under FED. R. CIV. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

215. Defendants' wrongful actions are generally applicable to the class members as a whole, for which plaintiff seeks, *inter alia*, damages and equitable remedies.

216. Absent a class action, defendants would retain the benefits of their wrongdoing despite their serious violations of the law and infliction of harm on plaintiff and class members.

IX. ANTITRUST IMPACT

217. During the relevant period, plaintiff and members of the direct purchaser class purchased substantial amounts of ACTOS and ACTO*plus* met directly from Takeda and/or purchased substantial amounts of generic versions of ACTOS and ACTO*plus* met directly from generic manufacturers.

218. As a result of defendants' illegal conduct, members of the direct purchaser class were compelled to pay, and did pay, artificially inflated prices for their drug requirements on these purchases. Those prices were substantially greater than the prices that members of the direct purchaser class would have paid absent the illegal conduct alleged herein, because: (1) the price of ACTOS and ACTO*plus* met was artificially inflated by defendants' illegal conduct; (2) direct purchaser class members were deprived of the opportunity to purchase lower-priced generic versions of ACTOS and ACTO*plus* met sooner; and/or (3) the price of generic ACTOS and ACTO*plus* met was artificially inflated by defendants' illegal conduct.

219. As a consequence, plaintiff and members of the direct purchaser class have sustained substantial losses and damage to their business and property in the form of

overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. IMPACT ON INTERSTATE COMMERCE

220. At all relevant times, Takeda manufactured, promoted, distributed, and sold substantial amounts of ACTOS and ACTO*plus* met in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

221. At all material times, defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of ACTOS and ACTO*plus* met and their generic equivalents.

222. In furtherance of their efforts to monopolize and restrain competition, defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

XI. MONOPOLY POWER AND MARKET DEFINITION REGARDING ACTOS

223. Takeda wrongfully acquired and used market power over the market for ACTOS.

224. At all relevant times, Takeda had market power over ACTOS and its generic equivalents because it had the power to maintain the price of ACTOS at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

225. A small, but significant, non-transitory price increase above the competitive level for ACTOS by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

226. ACTOS does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTOS. Other oral Type 2 diabetes medicines are not AB-rated to ACTOS, cannot be automatically substituted for ACTOS by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to ACTOS, and thus, are not economic substitutes for ACTOS.

227. ACTOS is not reasonably interchangeable with any products other than AB-rated generic versions of ACTOS.

228. ACTOS is part of the Type 2 diabetes drug class called thiazolidinediones. Thiazolidinediones, like a few other antidiabetic classes of drugs, are often referred to as "insulin sensitivity enhancers" due to their ability to decrease the body's resistance to insulin. Unique to thiazolidinediones, however, is that they increase certain levels of proteins – those that are more sensitive to insulin – and thus are the primary means by which a patient's blood sugar levels may be lowered. Due to their differing effect within the body, thiazolidinediones are significantly unique in their efficacy, safety, and side effect profile. These attributes play a critical role in doctors' selection of the most appropriate antidiabetic for a particular patient.

229. Due to, among other reasons, doctors' perception of ACTOS's lower association with heart failure, death, and liver toxicity, ACTOS is significantly differentiated from other drugs in the thiazolidinedione class. For these and other clinical reasons, substantial numbers of doctors prefer ACTOS to other thiazolidinedione drugs (*e.g.*, Avandia (rosiglitazone)). For example, according to some studies patients aged 65 and older who take Avandia (rosiglitazone)

have a higher rate of death and a greater risk of heart failure when compared with similar patients taking ACTOS.

230. Functional similarities between ACTOS and non-ACTOS thiazolidinedione products are insufficient to permit inclusion of those other thiazolidinedione products in the relevant market with ACTOS. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other thiazolidinedione product (except for AB-rated generic ACTOS) will take away sufficient sales from ACTOS to prevent Takeda from raising or maintaining the price of ACTOS above levels that would prevail in a competitive market.

231. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTOS. At all relevant times, Takeda's price for ACTOS was at least 60% above its marginal cost of production and at least 40% above its marginal cost including marketing costs. Takeda never lowered the price of ACTOS in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

232. Takeda needed to control only ACTOS and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTOS at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of ACTOS would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTOS.

233. Takeda knew that entry of a generic version of ACTOS would be a uniquely significant market event. Takeda predicted that, unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTOS would

take substantial unit sales from Takeda. For example, ACTOS did not lose substantial sales when generic versions of other branded Type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTOS would immediately cause branded ACTOS to lose well more than half of its unit sales. Likewise, Mylan, Ranbaxy, Actavis, and Teva estimated that their generic versions of ACTOS would take essentially all of their sales away from branded ACTOS and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

234. Takeda, Mylan, Teva, Ranbaxy, and Actavis predicted that the competitive impact of generic ACTOS products would be substantial. Among other things, defendants predicted that the availability of generic ACTOS would deliver well more than a billion dollars of savings to consumers.

235. At all relevant times, Takeda sold ACTOS at prices well in excess of its marginal costs and the ACTOS competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of plaintiff and the ACTOS class members.

236. Takeda had, and exercised, the power to exclude and restrict competition to ACTOS and its AB-rated bioequivalents.

237. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

238. To the extent plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, plaintiff alleges that the relevant product market is oral pioglitazone hydrochloride for the treatment of adults with Type 2

diabetes (*i.e.*, ACTOS and its AB-rated generic equivalents). At all relevant times, Takeda profitably maintained the price of pioglitazone hydrochloride well above competitive levels.

239. The relevant geographic market is the United States and its territories.

240. At all relevant times prior to generic entry, Takeda's market share in the relevant geographic market was 100%, confirming its monopoly power. Takeda continued to possess substantial market share and market power after generic entry.

XII. MARKET POWER AND MARKET DEFINITION REGARDING ACTO*PLUS* MET

241. Takeda wrongfully acquired and used market power over the markets for ACTO*plus* met.

242. At all relevant times, Takeda had market power over ACTO*plus* met and its generic equivalents because it had the power to maintain the price of ACTO*plus* met at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

243. At all relevant times, a small, but significant, non-transitory price increase above the competitive level for ACTO*plus* met by Takeda would not have caused a loss of sales sufficient to make the price increase unprofitable.

244. At competitive price levels ACTO*plus* met did not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of ACTO*plus* met. Other oral Type 2 diabetes medicines are not AB-rated to ACTO*plus* met, cannot be automatically substituted for ACTO*plus* met by pharmacists, do not

exhibit substantial cross-price elasticity of demand with respect to ACTO*plus* met, and thus, are not economic substitutes for ACTO*plus* met.

245. ACTOS is not reasonably interchangeable with any products other than AB-rate generic versions of ACTOS.

246. For clinical reasons, ACTO*plus* met is sufficiently unique from other Type 2 diabetes drugs as it is specifically targeted to, and taken by, patients who have not sufficiently improved their blood sugar levels by taking either metformin or pioglitazone alone.

247. Functional similarities between ACTO*plus* met and non-ACTO*plus* met Type 2 diabetes drug products are insufficient to permit inclusion of those other Type 2 diabetes drug products in the relevant market with ACTO*plus* met. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other Type 2 diabetes drug product (except for AB-rated generic ACTO*plus* met) will take away sufficient sales from ACTO*plus* met to prevent Takeda from raising or maintaining the price of ACTO*plus* met above levels that would prevail in a competitive market.

248. At all relevant times, the existence of other products designed to treat adults with Type 2 diabetes did not significantly constrain Takeda's pricing of ACTO*plus* met. At all relevant times, Takeda's price for ACTO*plus* met was at least 60% above its marginal cost of production and at least 40% above its marginal cost, including marketing costs. Takeda never lowered the price of ACTO*plus* met in response to the pricing of other branded treatments for Type 2 diabetes (or the generic versions of such medications).

249. Takeda needed to control only ACTO*plus* met and its AB-rated generic equivalents, and no other products, to profitably maintain the price of ACTO*plus* met at supracompetitive levels. Only the market entry of a competing, AB-rated generic version of ACTO*plus* met would have rendered Takeda unable to profitably maintain supracompetitive prices for ACTO*plus* met.

250. Takeda knew that entry of a generic version of ACTO*plus* met would be a uniquely significant market event. Takeda predicted that unlike the entry of other branded treatments for Type 2 diabetes (or the generic versions of such medications), entry of generic ACTO*plus* met would take substantial unit sales from Takeda. For example, ACTO*plus* met did not lose substantial sales when generic versions of other branded type 2 diabetes drugs entered the market at low prices. But Takeda predicted that entry of generic ACTO*plus* met would immediately cause branded ACTO*plus* met to lose well more than half of its unit sales. Likewise, Mylan and Teva estimated that their generic versions of ACTO*plus* met would take essentially all of their sales away from branded ACTO*plus* met and few, if any, sales from other branded Type 2 diabetes drugs (or generic versions of such medications).

251. Takeda, Mylan, and Teva predicted the competitive impact of generic ACTO*plus* met products would be substantial. Among other things, defendants predicted that the availability of generic ACTO*plus* met would deliver hundreds of millions of dollars of savings to consumers.

252. At all relevant times, Takeda sold ACTO*plus* met at prices well in excess of its marginal costs and ACTO*plus* met's competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of plaintiff and the ACTO*plus* met class members.

253. Takeda had, and exercised, the power to exclude and restrict competition to ACTO*plus* met and its AB-rated bioequivalents.

254. Takeda, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections, as well as the high cost of entry and expansion.

255. To the extent plaintiff is legally required to prove market power circumstantially by first defining a relevant product market, plaintiff alleges that the relevant product market is a fixed unit dose of oral pioglitazone hydrochloride and biguanide for the treatment of adults with Type 2 diabetes (*i.e.*, ACTO*plus* met and its AB-rated generic equivalents). During all relevant times, Takeda profitably maintained the price of ACTO*plus* met well above competitive levels.

256. The relevant geographic market is the United States and its territories.

257. At all relevant times prior to generic entry, Takeda's market share in the relevant geographic market was 100%, confirming its market power. Takeda continued to possess substantial market share and market power after generic entry.

XIII. MARKET EFFECTS AND DAMAGES TO THE CLASSES

258. But for the anticompetitive conduct alleged above, generic competition for ACTOS would have begun as early as January 17, 2011, and generic competition for ACTO*plus* met would have begun as early as February 25, 2011.

259. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting ACTOS and ACTO*plus* met from generic competition. Defendants' unlawful conduct was designed to, and did, discourage rather than encourage competition on the merits. Such conduct was undertaken for the anticompetitive purpose of forestalling generic competition.

260. Defendants' exclusionary conduct delayed generic competition, and unlawfully allowed Takeda to sell its branded drug products free from competition. But for this wrongful conduct, one or more generic competitor would have begun marketing AB-rated generic versions of these drugs much sooner than they actually were marketed.

261. Other generic manufacturers seeking to sell AB-rated generic versions of ACTOS and ACTO*plus* met, including Mylan, Teva, Actavis, and Ranbaxy all had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic manufacturers would have been ready, willing and able to effectuate earlier launches of their generic versions, were it not for defendants illegal and unlawful acts and conspiracies.

262. Defendants' unlawful actions and anticompetitive conduct allowed Takeda to maintain a monopoly and exclude competition in the markets for ACTOS and ACTO*plus* met, and their generic equivalents, and to maintain supracompetitive prices for both ACTOS and ACTO*plus* met, to the detriment of plaintiff and the members of the direct purchaser class. Defendants' anticompetitive conduct delayed and impaired generic competition and unlawfully enabled Takeda to sell ACTOS and ACTO*plus* met without timely generic competition.

263. Typically, generic drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of a branded drug for some or all of their purchases. As more generic drug manufacturers enter the market, prices for generic versions of a branded drug predictably plunge even further due to competition between the generic drug manufacturers, and, correspondingly, the branded drug loses even more market share to the generics.

264. This price competition enables all purchasers of the drug to (i) purchase generic versions of a drug at substantially lower prices, (ii) purchase generic equivalents of the drug at a lower price, sooner, and (iii) purchase the branded drug at a reduced price. Consequently, branded drug manufacturers have a keen financial interest in delaying and impairing the onset of generic drug competition, which, in turn causes purchasers to experience substantial increases in costs.

265. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets by the defendants anticompetitive conduct, direct purchasers, such as plaintiff and members of the class, would have paid less for these drugs by (i) receiving discounts on their remaining brand purchases of ACTOS and *ACTOplus* met; (ii) substituting less-expensive AB-rated generic ACTOS and/or ACTO*plus* met for the more expensive branded ACTOS and/or ACTO*plus* met, and/or (iii) purchasing generic ACTOS and/or ACTO*plus* met at lower prices sooner.

266. Moreover, due to defendants' anticompetitive conduct, other generic drug manufacturers were discouraged from and/or delayed in (i) developing and marketing their own generic versions of ACTOS and/or ACTO*plus* met, and/or (ii) challenging the validity or infringement of Takeda's patents in court.

267. At all relevant times during the class period, plaintiff and the direct purchaser class members directly purchased substantial amounts of ACTOS and/or ACTO*plus* met. As a direct and proximate result of defendants' illegal conduct, plaintiff and the direct purchaser class members were compelled to pay, and did pay, artificially inflated prices for ACTOS and/or ACTO*plus* met and their generic equivalents.

268. As a direct and proximate result of defendants' unlawful anticompetitive scheme and wrongful conduct, plaintiff and the direct purchaser class members have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for ACTOS and/or ACTO*plus* met and their generic equivalents, the exact amount of which will be proven at trial.

269. Defendants' unlawful conduct deprived plaintiff and the direct purchaser class members of the benefits of competition that the antitrust laws were designed to ensure.

XIV. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 1 AGREEMENT RESTRAINING TRADE (Against Takeda and Mylan)

270. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

271. Defendants Takeda and Mylan have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

272. On or about March 15, 2010 and at times prior to the formal execution thereof, Takeda and Mylan entered into the Mylan Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Mylan substantial consideration in exchange for Mylan's agreement to delay bringing its generic versions of ACTOS and ACTO*plus* met to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition; (c) fix the price

at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; (d) allocate a substantial portion of United States generic ACTOS and ACTO*plus* met sales to Mylan during the first 180 days of generic sales; and (e) allow Mylan the ability to immediately enter the ACTO*plus* met market on a date certain if either (i) branded sales dipped below a specified threshold as soon or (ii) any other generic manufacturer brought a generic version of ACTO*plus* met to market.

273. The Mylan Exclusion Payment Agreement harmed plaintiff and the class as set forth above.

274. The Mylan Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

275. Takeda and Mylan are *per se* liable for the Mylan Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

276. The agreement between and among Takeda and Mylan and their conduct under the Mylan Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

277. As a direct and proximate result of Takeda's and Mylan's anticompetitive conduct, as alleged herein, plaintiff and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM II: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Actavis)

278. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

279. Defendants Takeda and Actavis have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

280. On or about March 15, 2010 and at times prior to the formal execution thereof, Takeda and Actavis entered into the Actavis Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Actavis substantial consideration in exchange for Actavis's agreement to delay bringing its generic version of ACTOS to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition for five years or more; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; and (d) allocate a substantial portion of United States generic ACTOS and ACTO*plus* met sales to Actavis during the first 180 days of generic sales.

281. The Actavis Exclusion Payment Agreement harmed plaintiff and the class as set forth above.

282. The Actavis Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

283. Takeda and Actavis are *per se* liable for the Actavis Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

284. The agreement between and among Takeda and Actavis and their conduct under the Actavis Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

285. As a direct and proximate result of Takeda's and Actavis's anticompetitive conduct, as alleged herein, plaintiff and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM III: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Ranbaxy)

286. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

287. Defendants Takeda and Ranbaxy have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

288. On or about March 15, 2010 and at times prior to the formal execution thereof, Takeda and Ranbaxy entered into the Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Ranbaxy substantial consideration in exchange for Ranbaxy's agreement to delay bringing

its generic version of ACTOS met to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; and (d) allocate a substantial portion of United States generic ACTOS and ACTO*plus* met sales to Ranbaxy during the first 180 days of generic sales.

289. The Ranbaxy Exclusion Payment Agreement harmed plaintiff and the class as set forth above.

290. The Ranbaxy Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

291. Takeda and Ranbaxy are *per se* liable for the Ranbaxy Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

292. The agreement between and among Takeda and Ranbaxy and their conduct under the Ranbaxy Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

293. As a direct and proximate result of Takeda's and Ranbaxy's anticompetitive conduct, as alleged herein, plaintiff and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM IV: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Takeda and Teva)

294. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

295. Defendants Takeda and Teva have engaged, and continue to engage, in an unlawful contract, combination or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

296. On or about December 22, 2010 and at times prior to the formal execution thereof, Takeda and Teva entered into the Teva Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Takeda agreed to pay Teva substantial consideration in exchange for Teva's agreement to delay bringing its generic version of ACTOS and ACTO*plus* met to the market, the purpose and effect of which were to: (a) allocate 100% of the market for ACTOS and ACTO*plus* met products in the United States to Takeda; (b) prevent the sale of generic versions of ACTOS and ACTO*plus* met in the United States, thereby protecting ACTOS and ACTO*plus* met from generic competition for five years or more; (c) fix the price at which direct purchasers would pay for ACTOS and ACTO*plus* met products at supracompetitive levels; and (d) allocate a substantial portion of United States generic ACTO*plus* met sales to Ranbaxy during the first 180 days of generic sales.

297. The Teva Exclusion Payment Agreement harmed plaintiff and the class as set forth above.

298. The Teva Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

299. Takeda and Teva are *per se* liable for the Teva Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

300. The agreement between and among Takeda and Teva and their conduct under the Teva Exclusion Payment Agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

301. As a direct and proximate result of Takeda's and Teva's anticompetitive conduct, as alleged herein, plaintiff and the class were harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

CLAIM V: VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION AND MONOPOLISTIC SCHEME
(Against Takeda)

302. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

303. At all relevant times, Takeda possessed substantial market power (i.e., monopoly power) in the relevant market. Takeda possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

304. Through its overarching anticompetitive scheme, as alleged above, Takeda willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured plaintiff and the class.

305. It was Takeda's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

306. The natural and probable consequence of Takeda's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

307. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Takeda would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

308. Takeda's scheme harmed competition.

309. There is and was no cognizable, non-pretextual procompetitive justification for Takeda's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable such justification that Takeda were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

310. As a direct and proximate result of Takeda's illegal and monopolistic conduct, as alleged herein, plaintiff and the class were harmed.

CLAIM VI: VIOLATION OF 15 U.S.C. § 1
CONSPIRACY TO MONOPOLIZE
(Against all defendants)

311. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

312. At all relevant times, Takeda possessed substantial market power (i.e., monopoly power) in the relevant market. Takeda possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

313. Through the overarching anticompetitive scheme, including the agreements (and attendant payments) between Takeda, on the one hand, and Mylan, Actavis, Ranbaxy, and Teva on the other, the defendants conspired to maintain Takeda's monopoly power in the relevant market in order to block and delay market entry of AB-rated generic versions of ACTOS and ACTO*plus* met. The unlawful agreements between Takeda and the generic defendants allocated all sales of ACTOS and ACTO*plus* met and their AB-rated generic equivalents in the United States to Takeda; delayed the sales of generic ACTOS and ACTO*plus* met products; and fixed the price at which plaintiff and members of the class would pay for ACTOS and ACTO*plus* met and/or their AB-rated generic equivalents at the higher, branded price.

314. The goal, purpose and/or effect of the conspiracy was to maintain and extend Takeda's monopoly power in the United States market for pioglitazone hydrochloride tablets and for the fixed dose combination product containing both pioglitazone hydrochloride and metformin in violation of Sherman Act Section 1, 15 U.S.C. § 1. The conspiracy prevented and/or delayed generic competition to ACTOS and ACTO*plus* met and enabled Takeda to continue charging supracompetitive prices for ACTOS and ACTO*plus* met without a substantial loss of sales.

315. Defendants knowingly and intentionally conspired to maintain and enhance Takeda's monopoly power in the relevant market.

316. Defendants specifically intended that their conspiracy would maintain Takeda's monopoly power in the relevant market, and injured American Sales and the class thereby.

317. Each defendant committed at least one overt act in furtherance of the conspiracy, including:

- Takeda paid each generic defendant to stay off the market.

- Each of Mylan, Actavis, Ranbaxy, and Teva agreed to stay out of the market for pioglitazone hydrochloride tablets until August 17, 2012.
- Takeda on the one hand, and each of Mylan, Actavis, and Ranbaxy on the other, all agreed that if another generic manufacturer launched a generic version of ACTOS before August 17, 2012, then Mylan, Actavis, and Ranbaxy could also immediately come to market.
- Each of Mylan, Actavis, and Ranbaxy agreed to drop their patent challenges, including any efforts to break the bottleneck created by the listing of the Takeda patents in the Orange Book and the Exclusion Payment Agreements.
- Teva agreed to stay out of the market for the fixed dose combination product containing both pioglitazone hydrochloride and metformin until the date on which Mylan entered.

318. As a direct and proximate result of the defendants' concerted conduct, as alleged herein, plaintiff and the class were injured.

XV. DEMAND FOR JUDGMENT

WHEREFORE, ASC, on behalf of itself and the class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare ASC as a representative of the class;

B. Enter joint and several judgments against the defendants and in favor of ASC and the class;

C. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

D. Award ASC and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by the defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

XVI. JURY DEMAND

Pursuant to Fed. Civ. P. 38, ASC, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: April 27, 2015

Respectfully Submitted,

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